EPIDEMIOLOGY RESEARCH NEEDS RELATED TO THE RADIOIFREQUENCY ENERGY FROM WIRELESS PHONES

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(CRADA)

Between
FOOD AND DRUG ADMINISTRATION'S
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
(CDRH)

and

CELLULAR TELECOMMUNICATIONS INDUSTRY ASSOCIATION (CTIA)

May 2, 2001
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Meeting held at:

Marriott Kingsgate Conference Center
151 Goodman Drive
Cincinnati, Ohio 45219

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DR. OWEN: This is the second meeting, the first of which was a couple weeks ago, stemming from the research and development agreement with the Cellular Telecommunications and Internet Association. And that agreement is structured in three parts. And FDA's role in any of these parts is to provide the -- a scientific and technical oversight.

The actual administration of research, funding administration of research is being done directly by CTIA.

The first activity under this CRADA was a meeting we had in August on in vitro micronucleus assays. We had a meeting, somewhat larger meeting, where we -- like this one. The purpose was to bring in topic experts for scientific and technical input.

And then in September, we sent to CTIA some specific recommendations of research to follow-up earlier work in micro-nucleus assay with RF, wireless phone RF exposures.

They basically stapled to the front of that a request for proposals, and put it out in

advertisements and got several proposals to respond to those research recommendations that FDA had sent to CTIA.

Then they packed up the proposals and sent them to us and said, what do we do. And, because, again,

it was our job to review these proposals for their scientific and technical merit, as well as their responsiveness to the recommendations we'd sent in the first place.

And they're in the -- CTIA is now in the process of actually executing contracts to do that research. Once the contracts have been signed, then we basically promised the GAO that we would prepare a public document that allows people to see to what degree -- whether and to what degree CTIA was responsive to our recommendations.

So the second -- that was the first part of the CRADA organization. The second part is this epidemiology work. And the third part is a broader view to look for other possible mutual topics, topics of mutual interest for follow-up. Mutual interest between FDA and CTIA.

But because the CRADA was established as a follow-up to work that CTIA had funded earlier and was set up specifically for them to follow up the couple of

positive results done in their earlier funding and research, they want, specifically, advice on how to follow up the micro-nucleus work and the epidemiology work of Muscat, et al, that was published in December.

So the goal of this meeting, again, is to

collect input on what would be the best type of follow-up work to do for that -- for the case control study of Muscat and co-workers.

The scope of our discussions can encompass all RF epidemiology topics. But it's our -- our primary task is to advise CTIA how to follow up the work of Muscat and co-workers.

As I said, this is the second of two similar meetings. The meeting two weeks ago, we had -- let's see. We had Ken Rothman, Pete Inskip, Mary McBride, Greg was -- Greg and Abiy and I were here before. Bob Rinsky, Barb Grajewski. Close?

DR. BOWMAN: Good job.

DR. OWEN: John Moulder and Howard Bassen. Did I miss anybody?

MR. DESTA: Q. Balzano.

DR. OWEN: Oh, and Q. Of course, Q. Balzano. And had a very, very interesting day and a half of discussion.

DR. BOWMAN: Was Ken Rothman there? Did you mention him?

DR. OWEN: Yes.

DR. LOTZ: He was there.

DR. OWEN: He was there. I think I mentioned him. And what I was thinking today was, rather

than try and re-cap what we discussed there, just to take sort of the same approach, which was a very free-form discussion. And between me taking notes and, more importantly, the transcript that's being made to collect any input we can get on follow-up.

I wasn't sure that I wanted to try and influence today's discussion by talking about what happened before. But, of course, some of us were there before, so that might naturally happen to some degree.

And like the micro-nucleus stuff we did earlier, then after this is done, it's FDA's job to go back and come up with the recommendations to give to CTIA for follow-up work.

The micro-nucleus meeting that we had in August was a lot different in structure, actually, because there we were talking about work from a couple different groups, and none of it had been published yet. And so we had detailed presentations by the couple of investigators, so that the people sitting around the table would know what they were reacting to.

In this case, several things have been published in the open literature recently. And I think you're all aware of the literature. So I don't think it's necessary to go into any kind of review of those results,

except to the extent that it gives context to whatever

kind of thought you have on follow-up.

The last time that we did this, after I -- you know, at the beginning, after I went through some of these introductory background comments, Pete Inskip sort of kicked off the discussion. And that was useful, since his was the other recent case control study. And so he was in a good position to get things rolling.

By the way, I would mention that we tried to get Josh Muscat at one of these two meetings and thought we had him for one of the meetings, then he had a change in schedule. So we're going to try and pick up input from him by correspondence.

The same goes for Andrews Albalm (phonetic). We had him scheduled to come last time, and he had to back out at the last minute.

So this is a very diffuse information collection process. At this point, since I'm supposed to be the one collecting information rather than giving information, I'd like to see if anybody would like to start anywhere with ideas about what they think -- where

they think we stand after the publication of the Muscat Study and the Inskip Study, and what type of areas of follow-up might be needed.

DR. KACZMAREK: Where we stand, we now have evidence against the short-term effects, specifically

for brain cancer. I mean, the two case control studies really have similar results; that is, you know, of Inskip and Muscat. I mean, they're simply in that context. It was not an association between exposure to mobile phones and to brain cancer.

But I think both of those studies have pretty similar limitations. The largest limitation is the limited duration of use of the study subjects. I think in the Muscat case, it's less than three years. I think in Inskip, as well.

So we don't have evi -- the ability within the context of those studies to address potential long-term effects.

And I think another limitation of those particular studies is that they're really focused on analog users and not digital users. I think that's true -- and again, that's true in both cases. In the Inskip Study, they don't go out of their way to tell us whether -- what the portion of users were actually digital users as opposed to analog users. But they make a statement

that they presume that most of the study population, given the time frame of the study, actually consists of analog users.

So I think there's a real need to go forward and look at digital users as well.

DR. KHEIFETS: I mean, I agree with everything that was said. But in addition, I think that the exposure assessment is a huge problem. I mean, latency certainly is the biggest problem.

But in addition to that, even if the latency was there, I think the exposure assessment, at this point, is so poor that the study is just going to have to be non-definitive by that nature.

And so I think real progress needs to be made in exposure assessment work. And until that is done, I don't know how to really move forward, other than just establishing cohorts for future follow-up and trying to just get as much relevant information now as possible.

It's sort of akin to appliance use studies, in my opinion, which are just so non-informative because the -- their ability and exposure is so great and it's not captured, certainly, by the questionnaire means.

And so, I mean, that's where we're stuck, really, is that there needs to be both meters and develop that would -- a case in some ways try to capture exposure.

And then also, a lot of methodological work to try to see how this exposure or these meters can be implemented in the study and what kind of exposure, surrogate information can be collected to validate the assignment of people.

DR. BOWMAN: Maybe I can give a little

overview of what's going on in the IARC Study that's mentioned in the report of the independent expert group.

As you may know, the International Agency for Research on Cancer is doing a multi-national study, case-control study, of brain cancers, neck -- everything from the neck up, also leukemias, and use of mobile phones.

And I've been on the international committee that's been working on the exposure assessment. And the exposure assessment -- well, first, if you think about exposures to the radiation from mobile phones, there's a number of components. The questionnaires can deal with, what is the phone and what network the user is subscribing to and how frequently they use the phones.

And, of course, this is all recall. So there's the usual recall biases to be concerned with. And also, a lot of this is done with interviews of very sick people. And so, again, there's -- there's problems in recall there.

But even with that information, the phone

-- the actual energy absorbed in the brain, is a function of how the phone is held, whether the antenna's close to the skull or further away. It's a function of how close -- what power is being emitted by the phone, which is a function of how close it is to the base station it's

talking back and forth with. And it's also a function of the distribution of the radiation from the antenna and from the body of the phone.

And so how this Interphone Study, this 13-country case control study is handling those issues is, in addition to the questionnaire, which is a very -- it's a state-of-the-art questionnaire. It's being -- it's programmed to work on laptop computers. It's computer-assisted. So in identifying the phone, the subject can look at pictures of different models of phones on the computer screen. And the program makes this lengthy interview as effective as modern technology allows?

DR. KHEIFETS: How long is an interview?

DR. BOWMAN: I think it runs over an hour. So it's definitely a strain on somebody who's very sick with therapy for brain cancer. But it -- interviews have been going on for the better part of a year now. And the epidemiologists report that it's working reasonably well.

DR. KHEIFETS: Do they have a proxy? Do they do proxies for any of them?

DR. BOWMAN: Proxies in what sense?

DR. KACZMAREK: With patients that are --

DR. BOWMAN: Oh, I see --

DR. KACZMAREK: -- experiencing --

DR. BOWMAN: -- what you're saying.

DR. KACZMAREK: -- unfortunately --

DR. KHEIFETS: Or unable to answer --

DR. BOWMAN: I can't answer that right off -- off the top. The -- my involvement, as I said, has been with the exposure assessment committee. We meet with the epidemiologists occasionally.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: So I -- I really can't give you a complete overview of the epidemiology.

But in -- so in addition to the questionnaire, to deal with the power transmission question, as well as questions of recall, they're doing a supplemental study with volunteers using software-modified phones that can store information on the power transmitted, whether it's analog or digital transmission and other related questions of transmissions, and log that over time.

So the recruit volunteers, according to a sampling scheme that will cover variables such as their service provider, whether they're urban or rural, things like that, they administer the questionnaire to see what their recall is as to their phone use, and then they give them the phone. And the phone actually logs their phone use. And they have cooperation with the service

25 providers, so they can get the phone company records.

And putting the two together allows us to get -- the epidemiologists can test peoples' recall on these parameters.

And then the data collected gives distribution of power usage by the variables I just mentioned. So that's the second component.

And the third component is, given the model of phone, what is the energy distribution in the brain or the SAR. And that's where Joe Viart of French Telecom is on the Exposure Assessment Committee, and is providing us with modeling results that we can use to be part of the exposure assessment.

So at our last meeting in December, we scoped out how to put all that information together to get an estimate of energy absorbed for the subjects. And, of course, this is -- involves a lot of modeling, so it would have a lot of uncertainty. But at least it sort of blocks out the different elements required of exposure assessment.

And I guess the last thing I just want to

throw in is that the software-modified phones, obviously, could be used for prospective studies, as well as for, you know, the supplemental data collection that -- to supplement the retrospective study.

DR. KACZMAREK: Is there a use of billing

records in this study to estimate frequency and duration in the past?

DR. BOWMAN: There's been -- the availability of billing records is irregular. I'm -- you know, secondhand, I've certainly heard that discussed a lot. But the bottom line was that that could not be used reliably across 13 different countries.

DR. OWEN: Is it the case that billing records, in Europe, are typically one-sided? Meaning only capturing outgoing calls. I've heard that.

DR. BOWMAN: Again, I really can't give you details, no. It's not something I've made a particular study on. And when I -- when I came on the scene, the -- the decision to use interviews rather than billing records had long since been made.

DR. KHEIFETS: Do you recall, by any chance, if they have like any red herring questions to -- in the questionnaire, or just really questions to try to assess recall bias?

DR. BOWMAN: I do have the paper version

of the questionnaire. I don't recall any right offhand. But people are welcome to look at it and, you know -- I will mention one additional thing about the questionnaire.

Is that the exposure assessment is not just focused on cell phones, but encompasses all radio frequency microwave

exposures, particularly occupational or also walkee-talkees and amateur radios. And also extremely low frequence, power frequency exposures.

So it's -- and while at first blush, that might seem to be sort of, you know, a totally different band width and only argumenably relatable, it's sort of sobering to realize that in the digital phone, the digital pulse rate is in the extremely low frequency region. So if some biological structure acts like a radio transmitter and demodulates the ELF pulses from the radio frequency carrier wave, it would end up picking up a signal in the ELF range. And so direct ELF exposures might somehow interact.

So that's one rationale for looking at ELF exposures, as well as just the basic that there's already been some reported associations of ELF exposures with brain cancer.

DR. OWEN: Are there any restraints on

the
19 public availability of that questionnaire? Is it public
20 --
21 DR. BOWMAN: Not that I know of.
22 DR. OWEN: Okay.
23 DR. BOWMAN: But I guess I'd better ask
--
24 DR. OWEN: Okay.
25 DR. BOWMAN: Elizabeth Carter is the

principal investigator. -- before I --

DR. OWEN: Okay.

DR. BOWMAN: -- go ahead and distribute it.

DR. KACZMAREK: The question was raised whether it -- basically the choices between using only interviews or only billing records. And there may be merit in using a combination of both. In essence, the billing records may be a check on the patient's own history.

So the information that you obtain by interview may be verified through the use of billing records. So there might be considerable merit in the next generation of studies, in attempting to use both for exposure assessment in some fashion.

DR. BOWMAN: And the, like I said, the Interphone Study is using phone company records in the supplemental study, that they're using both concurrent billing records. Because if you know for sure the company is saving the data you want, you're better off than

relying on what they did 10, 20 years ago where, you know, their collection would have been motivated by simply commercial considerations and not necessarily getting the parameters of our important exposure assessment.

DR. LOTZ: These new phones, some refer to

them as dosimeter phones, seem like they really offer a lot in terms of new studies, because it turns out they can actually, not only record the time and the power emitted of the phone, they can actually even record which side of the head, laterality, which side of the head they were used on and even -- they even have the potential to record how close the phone is held to the face, by the use of their circuitry.

So they really -- they really offer a lot of potential.

DR. KACZMAREK: Probably the greatest limitation of a phone like that is the study would have to be perspective. You would lose the advantage of either a retrospective cohort study or a case control study which is, you know, essentially time. You can go back in time and generate greater periods, longer lengths of duration of exposure.

DR. LOTZ: Wouldn't they still be useful, Ron, though, in terms of validating peoples', at least, recall of what they do in that --

DR. KACZMAREK: Well, it's possible that --

DR. LOTZ: -- even in a retrospective sense? I mean, not that you can go back and test it back. But if you're collecting their recall of what they do and

then you compare, you know, at least maybe a short contemporary period what that technology can record as actual use.

DR. KACZMAREK: I think there'd certainly be a question there whether or not the frequency and duration of their usage had changed over time. I think that's a clear possibility.

DR. LOTZ: Well, yeah. Well, I think that's not only a possibility. That's --

DR. KACZMAREK: It's a probability, in essence.

DR. LOTZ: It -- the whole pattern of the use of cell phones is not only increasing numbers of customers, but increasing duration of use.

When -- when this sort of first all came up and FDA first had a discussion meeting like this about seven years ago now, there was data to indicate that the average user spent less than five minutes a day on their phone.

I don't know what the data shows now.

And
asking an industry person recently, they didn't seem to have that type of information at least characterized now. But it's got to be way -- a whole lot more than that. There still are, I'm sure -- well, maybe average, I don't know what you do with average. There are still, I'm sure,

a lot of people who do very little with their phone, have a phone but use it very little. But there's a whole other category of people that are using it an awful lot.

DR. KACZMAREK: It may also be a function of cost. The cost per minute has dropped precipitously over time.

DR. LOTZ: Sure. Yeah. Oh, yeah. Yeah.

DR. BOWMAN: And that's also relevant in terms of evaluating the two published epi studies, is that their high exposure group is around that five-minute-a-day average.

DR. OWEN: Yeah.

DR. BOWMAN: And so clearly you've got people that are just far off the area of exposure that they've assessed.

DR. LOTZ: Yeah, that's a really good point, Joe. Do you know, in the IARC Study -- well, I guess they're -- they'll take the cases they find and just partition them as --

DR. BOWMAN: Right.

DR. LOTZ: -- according to use, as opposed to -- if there were a cohort recruited, then you might want to go after --

DR. BOWMAN: Oh, yeah.

DR. LOTZ: -- for a future study, if --

DR. BOWMAN: Oh, well, right.

DR. LOTZ: -- you were recruiting a cohort, you'd want to go after some of those really high-end users.

DR. BOWMAN: Of course, in a case control study, you're doing it the other way around.

DR. LOTZ: Yeah, exactly. That's -- so you take what you get --

DR. BOWMAN: Right. Exactly.

DR. LOTZ: -- in that instance.

DR. BOWMAN: Your cases, of course, are the people that meet your disease criteria and your controls are either population controls or hospital controls, but, again, selected randomly out of your sampling parameter. And then the whole point of the data collection is to assess the exposures and compare the exposures.

DR. KHEIFETS: The other -- the other issue is how much of the phone is used by the subscriber and how much of it is used by somebody else, which is --

DR. LOTZ: Right.

DR. KHEIFETS: -- not going to be captured by the bill --

DR. BOWMAN: That's a billing record problem.

DR. KACZMAREK: Yeah, major limitation of billing records.

DR. KHEIFETS: Yeah, that's a billing record. And both of those studies, if I recall, were hospital controls, both Inskip and Muscat studies were hospital control?

DR. OWEN: I think so, yeah. I know Muscat was. I'm pretty sure Inskip was too.

DR. KHEIFETS: That's another issue, of course, which is the problem with those studies as hospital controls. I'm doing a little Andrews here, while he's not here.

DR. LOTZ: That's fine.

DR. OWEN: Yeah. We need him.

DR. KACZMAREK: Certainly, none of the --

DR. BOWMAN: Just refresh my memory. What are some of the problems with hospital controls?

DR. KHEIFETS: The problem basically is that they are not representative of the population. That they are, you know, selected in a different way. That they might be sick for --

DR. BOWMAN: Right.

DR. KHEIFETS: -- for a reason, that is --

DR. BOWMAN: That might be related to the exposure.

DR. KHEIFETS: Due to the use of the phones. I mean, you know, they may be -- maybe they are just sick and that's why they are not using the phones as much or they're using more or whatever.

DR. BOWMAN: Right.

DR. OWEN: You said something earlier, Leeka, about how damning the exposure assessment problem was to those earlier studies. So one might jump to the conclusion from that statement that at some point down the road, one could say, okay, we know enough more about exposure assessment and, by the way, we also have people in a high-use category that is 10 -- 10 to 100 times what the high-use category was in these earlier studies. Now's the time we should just basically go back and do a head and neck cancer case control study again. What do you think about that?

DR. KHEIFETS: Well, I mean, I think, unfortunately, the exposure assessment does not develop usually kind of in absentia of actual studies. I mean, the way the exposure assessment gets better and more is learned is the nature of any process.

And so if you do not do studies, just wait until exposure assessment sort of gets better, I mean, in some situations, it makes sense, but not really long term.

Because I think that the exposure assessment does not tend

to develop as much without the driving force of the study.

So you just kind of have to do some of the studies that do not have as good exposure assessment, learn from them, and then do better studies. And so maybe now is a good time to do all of those things, maybe not jump into the study necessarily. I'm not saying we would have to jump into the study. But do a lot of methodological and exposure assessment work, while wait and see and exposure accumulates, and so you could do a better job.

DR. OWEN: Okay. That's what I was just going to ask you. Do you consider it theoretically possible to do methodological and exposure assessment work and gain these improvements if you make a conscious decision to do that?

DR. KHEIFETS: Oh, I think definitely that's what you have to do. I mean, I think now is a good time to try to really do a lot of that work and -- and learn from it.

DR. LOTZ: So in --

DR. BOWMAN: And that's certainly what epi did in the past decade or so with extremely low frequencies, is that after the early crude epi studies raised the issue to the point of it being worth pursuing, they did have a program focused on developing better

instruments, understanding exposures, getting broad exposure data that laid the basis for epi studies to come.

And so a comprehensive program is not just a, you know, let's go out and do an epi study. A comprehensive program is to look at the exposure assessment overall. You know, identify what the important components are. See what's being done. See what needs to be done. Fill those gaps. Pilot them.

There's always surprises once you get new instrumentation to look at new questions, as well as the inevitable need to make things rugged enough in the field so that you can go out and collect data in bulk. So pilot them.

And that lays the, you know, the infrastructure for better epi studies in the future.

DR. KHEIFETS: There are other ongoing studies, either ongoing or planned; is that right? Do you have kind of a good understanding what's in the pipeline?

DR. OWEN: No. And that's actually a problem. I asked for that kind of input at the meeting a

couple weeks ago and got very little information, other than on the IARC Study.

DR. LOTZ: Actually, I don't know that anyone responded with or that I know. Now, whether there might be some things in other parts of the world --

DR. KHEIFETS: Yeah. I know that there is a -- unfortunately, I don't know exactly the status. But I'm, I think, an advisor to a study that Andrews is going to do in the U.K. But I don't --

DR. OWEN: This must be a proposed study.

DR. KHEIFETS: It's a proposed study.

DR. OWEN: Yeah.

DR. KHEIFETS: But I think it's more than proposed. I think it's --

DR. OWEN: Really?

DR. KHEIFETS: Well, I might be wrong.

DR. OWEN: Yeah. Well, I was thinking of the --

DR. BOWMAN: Is it focusing on --

DR. OWEN: I was thinking of the U.K. government program which just put out a very broad ranging request for proposals.

DR. KHEIFETS: Yeah.

DR. OWEN: But they're nowhere near the funding stage. But this may be funded by some other method.

DR. KHEIFETS: Well, unfortunately, I really don't know. I mean, maybe it is just a proposed study.

25 DR. OWEN: Well, I'll pound on Andrews

about that.

DR. LOTZ: I was going to say, that's a lead that can be followed up.

DR. KHEIFETS: So --

DR. BOWMAN: I had heard that the U.K. was doing occupational radio frequency study. And the tidbits I'd heard about it seemed that it was fairly well underway.

DR. OWEN: Do you know who the PI or anything would be on that?

DR. LOTZ: Is that Chadwick's work?

DR. OWEN: Phil moved to Gabriella's --

DR. BOWMAN: No, it's not. Chadwick is --

DR. LOTZ: Okay.

DR. BOWMAN: -- not involved in the epi that I know of.

DR. LOTZ: I guess -- I thought he was working on some exposure assessment. I thought it might be related. He wouldn't be the epi lead, obviously.

DR. OWEN: Well, I think he's recently moved to --

DR. LOTZ: Okay.

DR. OWEN: -- a different outfit. So --

DR. LOTZ: I didn't realize that either.

DR. OWEN: -- it -- he may be just

starting that or just -- probably just starting up on that. And that probably involved why he did that. Cause he left -- he left the government and went to that outfit that Gabriella, Camilla Gabriella -- is that her name?

DR. KHEIFETS: Who?

DR. LOTZ: Yeah, that's her name.

DR. KHEIFETS: Chadwick did?

DR. OWEN: Yeah. That's what I heard. I haven't spoken to him since this move occurred.

DR. KHEIFETS: Is there anything that's going on in terms of planning or potential for reference, or however that cohort is called? And that there is a cohort in the U.N. that --

DR. OWEN: Well, Ken would like to see it.

DR. KHEIFETS: But --

DR. LOTZ: But it's basically --

DR. KHEIFETS: It's basically dead.

DR. LOTZ: -- dead at this point, yeah.

DR. OWEN: Yeah. I mean, he started --

DR. LOTZ: That cohort --

DR. OWEN: He tried to start that study -- I think he first tried to pitch that study, working hard on pitching that study, at least ten years ago. I mean, before there was even a CTIA-funded program.

25 DR. LOTZ: But he also said in that two

weeks ago that I guess the legal problems they ran into on the billing records hasn't even been fully resolved yet.

DR. OWEN: Yeah, not fully resolved. The -- that -- the Busse case has become a class action suit. And so the problems that brought that study to a halt in the first place are not --

DR. KHEIFETS: -- not resolved.

DR. OWEN: -- completely resolved, yeah.

DR. KACZMAREK: There is a retrospective cohort study from Johansen, et al., that's published in the National -- Journal of the National Cancer Institute, where they looked at 420,000 cellular telephone subscribers. And then they looked at the cancer incidence rate of matching with registry records. And they couldn't find an association between subscribing to a cellular phone and the overall incidents of cancer or the incidents of brain or nervous system cancer, salivary gland cancer or leukemia.

And, of course, there are a number of limitations to the study; the first of them being exposure assessment based solely upon subscribing. There's multiple use of the phone. It's not only used by the subscriber, but there's no attempt at all to assess exposures based on interviews.

Also, there's very limited duration of use

again. I think it's 3.1 years with a follow-up for all users. And the digital users only had 1.9 years work of follow-up. So again, they don't really address long-term issues.

But still, I think there is considerable merit in having a cohort study. As everyone's aware, cohort studies don't have the same limitations and strengths that case control studies do. For example, recall bias, which is a major problem in case control studies, or at least a major potential problem. It simply is not a problem in a cohort study.

And there probably is considerable merit in having a cohort study looking long term at these issues. Again, particularly due to the fact that with a cohort study, you can look at multiple endpoints and not just one disease at a time.

So whether we establish that cohort in the U.S., if that's possible, or if we establish it in Europe, there should be a cohort somewhere in the world, in essence, where we are looking at these issues.

DR. OWEN: Ron, what are the -- what do you lose if you do a retrospective cohort versus a prospective?

DR. KACZMAREK: Retrospective cohort studies -- well, again, you're not able to make your

exposure assessment contemporaneously. So you're going back in time. There could be some loss of information because of that.

Obviously, you're saving time in terms of the actual duration of the study, because you're allowing the people to accumulate exposures basically in the past. But you're not going to be able to monitor them, in essence, with a personal dosimeter going back in time, obviously.

DR. OWEN: Um-hmm.

DR. KHEIFETS: You're making an assumption -- you would have to make an assumption that the exposure assessment today is somehow reflective of what it was in the past. And with something that changes very rapidly, it's very difficult. So, you know, so that's the main issue.

DR. BOWMAN: And you can do prospective/retrospective cohort studies --

DR. KACZMAREK: Right.

DR. BOWMAN: -- or nested case control studies within a retrospective/prospective cohort, where you use some of the methodologies of both of them, but you do have the prospective component which can help validate your retrospective questionnaire data.

DR. OWEN: This is a question that's come

up with other people, so I'll bring it up again. As part of the whole exposure assessment problem or issue, the use of the phone, not only how much you use it or what you use it for, but also the way you hold it, do you think that any of the aspects of exposure assessment would differ between a U.S. cohort and a non-U.S. cohort; and, if so, do you have any ideas how they might differ?

And, I mean, there's the obvious ones of what is the carrier? what's the actual signal types? what are the models of phone? Which, in general terms, do usually vary between U.S. and other places. But I was thinking more in the other aspects.

DR. KHEIFETS: Well, that manages the amount -- I mean, both the amount of use and when it's used. I mean, it seems if you go to Europe, you have, in Italy, you have all those people on scooters, you know, trying to avoid --

DR. OWEN: Phone in one hand, an umbrella in the other hand is --

DR. KHEIFETS: So they might be holding

the phone differently just because they have to navigate at the same time, you know, is an example. And I think that easily could have happened. But on the other --

DR. BOWMAN: Well --

DR. KHEIFETS: And in Japan, you can't use

the phones on the bus or in any public place, basically. So, apparently, there has been a great reduction in the use of phones. And the young people have moved to little things where you get the messages. They're called --

DR. LOTZ: Text messages.

DR. KHEIFETS: -- electronically.

DR. OWEN: Right.

DR. KHEIFETS: And they just not using cell phones at all, or very little. I mean, a lot less, because they --

DR. LOTZ: Does --

DR. KHEIFETS: -- could communicate -- they want a constant connection, and they have it.

DR. LOTZ: Do those prohibitions, Leeka, pertain to like their train system and stuff too?

DR. KHEIFETS: I think so. I think you can't basically use them almost anywhere in public places. It says because they are annoying to other customers. That's, you know -- so they keep repeat -- I mean, I was on the bus to the airport for like two and a half hours or three hours, and they constantly broadcast that you can't use your phone because it might be annoying to --

DR. OWEN: It got annoying listening to that broadcast.

DR. KHEIFETS: Yeah.

DR. LOTZ: That's pretty radical, though, compared to like if you think about what the sort of emerging uses are in this country.

DR. KHEIFETS: Yeah, during the opera, somebody's phone is ringing all the time. No. But it's -- it's really -- I mean, I think that --

DR. LOTZ: But I mean that --

DR. KHEIFETS: -- especially the more young people, they said there is a great change in the behavior in terms of the use of the phone, because they have kind of got used to this idea of being connected to each other and to whatever other information that they want. And those little, I don't know -- they're not pagers. Whatever they are. But that, you know, allow you to kind of type back and forth are very popular.

DR. KACZMAREK: That raises an issue regarding study needs. There's obvious use of mobile phone among the pediatric population, yet those populations weren't included in the studies.

For example, in Inskip's Study, there were no subjects under the age of 18. I think there's a real need to look at the pediatric population.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: Ron, what would you -- I mean,

25 in -- given two things, I mean, sort of the question of

latency and also the health, normally lower incidents maybe. I'm assuming. I'm not an expert on those.

DR. KHEIFETS: It's not that different for --

DR. LOTZ: Not that different.

DR. KHEIFETS: Or maybe it is certainly less. But there's -- yeah.

DR. LOTZ: What I guess --

DR. KHEIFETS: Yeah, that's an excellent point. I mean, I think --

DR. LOTZ: Is there merit in -- in study -- even though they're such heavy users or at least the potential segment of them, is the difficulties in terms of just numbers of cases, duration, potential latency, that kind of thing, sort of an overriding factor not --

DR. KACZMAREK: Well, you're raising an important issue that, obviously, the incidents of cancer is lower in the pediatric age population than it would be in the adult population. And it does raise sample size issues that would have to be factored into the overall

privatization scheme. And I think that would be a major minus for studying it, because attempting to study it would be quite challenging.

If it's going to be a cohort, it has to be a very, very large cohort, for example. And I think we

need to be aware of that.

DR. OWEN: It sound --

DR. KACZMAREK: Or conversely, it would be certainly nice to have some data on the pediatric population as opposed to no data.

DR. KHEIFETS: But the latency might be shorter. And, you know, I -- I mean, I think there are definite advantages. Their other exposures might be more manageable. I mean, I think there could be a number of advantages that would help. But still, I mean --

DR. LOTZ: I mean, in a sense there -- it's appealing in, you know, looking after children is --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- appealing from a sort of --

DR. KHEIFETS: And especially, I mean, in Britain, they had a special advisory --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- not to --

DR. LOTZ: France has done the same thing.

DR. KHEIFETS: Right. So that, I mean, those -- probably you can do those studies already in those two countries.

DR. OWEN: Well, in particular, it sounds like that would be an important demarcation, if you were

doing one of these sort of combination

prospective/retrospective. I mean, obviously, you're going to have -- well, maybe not obviously. But I would suspect you're going to have huge differences in the type and amount of use, depending on whether you're a, you know, an unemployment teenager versus, say, a gainfully employed 30-year-old, something like that.

But if you're looking at the health of -- you're following the health of people that are in their, you know, 30 to 50 range, we would like to know something about those exposures that occurred in the past. And it might be radically different from the exposures that they were getting at the present.

DR. KHEIFETS: Right. Right.

DR. OWEN: So it brings up those issues that you were talking about earlier about the retrospective/prospective combination. So --

DR. KHEIFETS: Do really -- I mean, do kids use them -- they probably do at the age of, what, 13? What age?

DR. LOTZ: Junior high's big. I --

DR. OWEN: You see a lot of --

DR. KACZMAREK: Right.

DR. LOTZ: I was going to say --

DR. OWEN: -- press about it in the --

DR. KHEIFETS: Yeah.

DR. LOTZ: -- so 11, 12 --

DR. OWEN: -- junior high age, yeah.

DR. KHEIFETS: Right.

DR. LOTZ: -- kind of thing. I know I have a daughter who, a year ago, in eighth grade said -- came back from Christmas vacation and everybody was showing off their cell phones, even though they weren't even supposed to be allowed to have them out in school.

DR. KHEIFETS: Right.

DR. LOTZ: But I don't know. I mean, everybody was certainly --

DR. KHEIFETS: The peak is about age nine. The peak of pediatric brain tumors is about age nine. And pediatric considers -- is considered to, let's say 16, or 19.

DR. LOTZ: I haven't looked at the data in detail. The other thing, if you start getting down to those kinds of ages is, is there really -- appears to be some differences in SAR because of bone density of the skull and thing like that.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: That there's more penetration of energy into the --

DR. OWEN: There seems to be a lot of

controversy over that.

DR. LOTZ: Well, I think the controversy's over what age is really -- there's really a difference. Clearly in the very, you know, young child, five years old, whatever, there'd be a big difference in the modeling --

DR. OWEN: Yeah.

DR. LOTZ: -- what the modeling shows. So I think the controversy is when is -- how big is that difference is, you get -- when you get to 15, 16, 18 years old, it's probably not a meaningful difference, even though sometimes that concept gets generalized into, you know, don't let children use it because it becomes a rationale that probably isn't valid at that point.

But maybe with as young as, you know, nine, ten years old, it might still be meaningful.

Are there other issues in terms of studying minors that make a study very difficult in terms of access to the population, approvals --

DR. KACZMAREK: Well, certainly one major advantage of epidemiology is that we don't control the exposure. People voluntarily expose themselves in the context of an epidemiologic study.

DR. LOTZ: Okay.

DR. KACZMAREK: So since the exposure's

25 going on anyways, I don't think you have the same ethical

issue as you might have -- that might be raised in the context of some sort of clinical trial.

DR. LOTZ: Okay.

DR. KACZMAREK: Because this is an epidemiologic study, it's purely observational.

DR. BOWMAN: You would have the extra work of getting parental --

DR. KACZMAREK: Right. Yes. I mean, in terms --

DR. BOWMAN: -- consent, informed consent.

DR. KACZMAREK: -- of getting informed consent to participate in this study, it would be more challenging than for adults, without question. But I think it could still be done.

DR. BOWMAN: And there have been ELF studies where children were recruited, not across the board, but through sub-studies where they were recruited to wear meters.

DR. LOTZ: Um-hmm.

DR. KACZMAREK: I think that's an excellent point. There's a good track record in ELF of basically recruiting children to participate, as well as wearing personal dosimeters.

DR. BOWMAN: And if the actual

observation

is to give them a data collection phone, a dosimeter

phone, that, you know, would have the same exposures of what they're using already, there you're, you know, not creating an exposure --

DR. KACZMAREK: Right.

DR. BOWMAN: -- that isn't already existing. And I would think it would be okay with an institutional review board.

DR. OWEN: Particularly, I guess, if you didn't have any large incentives to change usage based on agreeing to participate and use such a phone.

DR. BOWMAN: Right.

DR. OWEN: I mean, if the phone came with a --

DR. KHEIFETS: -- free --

DR. BOWMAN: Right.

DR. OWEN: -- free calls, then you're encouraging them to increase their exposure.

DR. LOTZ: Right.

DR. OWEN: Which could be a problem to an IRP, you know.

DR. BOWMAN: Or if you gave them a phone where they didn't have one already.

DR. OWEN: That might, yeah.

DR. KACZMAREK: Right.

DR. BOWMAN: You'd have to somehow deal

with that issue, that if your cohort included people that did not have a phone but later got a phone, at what stage would you step in and give them the software-modified phone.

So there would be issues, but I don't know that they're totally insurmountable. I don't think they -- I mean, I think they could be handled, if not perfectly, at least reasonably well.

DR. LOTZ: I guess one of the things that would be an advantage is that because the population of users is so large now, you don't have to get a high percentage of who's using the product to get a substantial cohort.

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. BOWMAN: One concern with the exposure assessment is the use of the phone for basically keyboard transmission, because there the exposure to the head is,

you know, minuscule if you're working with it down here.

And that's one thing that I don't think the uniform study is tracking, you know, that I'm aware of.

DR. OWEN: Because the current SM phones don't -- the software-modified phones don't have text messaging capability, or -- cause I was thinking, if you

have one of these dos phones, as they're sometimes called,

certainly that phone would be sophisticated enough to know whether it's anywhere near a head, as opposed to in a hand being --

DR. LOTZ: Yeah. Apparently --

DR. OWEN: -- punched like a keyboard.

DR. LOTZ: -- from the capacitive aspects of the circuitry, they can tell that. But I don't know if they're made to be, you know, the web interactive --

DR. OWEN: Yeah.

DR. LOTZ: -- or text messaging.

DR. KHEIFETS: It even depends --

DR. BOWMAN: Well, certainly the dos phones could track that. I mean, be programmed to record what kind of transmission mode they're in, if it's voice --

DR. OWEN: Yeah.

DR. BOWMAN: -- or if it's data.

DR. KHEIFETS: The -- I mean, the similar question is with hands-free devices, right? I mean, if it's --

DR. BOWMAN: Well, there the use of hands-free devices is probed in the questionnaire. And they're asked to estimate the proportion of time they would use it with a hands-free device and what kind of device is it.

25 Is it a headset? Or is it a device that's made to go with

a car.

DR. KHEIFETS: Right.

DR. BOWMAN: So that is tracked there. What my concern was, in keeping about your description of the use of data transmission is that that question, I don't think, is -- is in the uniform questionnaire.

And there is a concern, it's more theoretical, I think, than truly serious. But in terms of the new technologies that are coming out, the wireless computer networks where laptop computers have transmitters, it wouldn't particularly affect the head, but it would be an exposure. How high an exposure, I don't know.

And over the course of a long study, there's always a potential for new technologies to come along that could produce compounding exposures.

DR. LOTZ: Conceivable in that -- in a case like that, Joe, which clearly exists here, that if you were doing cohort, that you might have to then increase the size of the cohort, so you'd still have a substantial segment of it, I guess you could say, that -- that had the type of -- was using the type of technology,

in other words, say at the head, that was critical to answering the question of the basic hypothesis.

In other words, if you have -- you set

out, you have a certain size cohort. And then a quarter of them end up using, you know, newer technologies that take it away from the head, would that -- would if you have a larger cohort to start with, is that sort of an attrition of the relevant cases? Or not cases, but subjects.

DR. BOWMAN: Well, I don't -- maybe Leeka should answer that. I'm not a direct epidemiologist.

DR. LOTZ: Well, I'm really --

DR. BOWMAN: My envision of a cohort is --

DR. LOTZ: -- posing that to the group.

DR. BOWMAN: -- you start with a definition of what your cohort is.

DR. LOTZ: Yeah.

DR. BOWMAN: And everybody that you can -- that meets that definition that you can recruit into the study, is part of the cohort.

DR. LOTZ: I guess what I'm --

DR. BOWMAN: And that's sort of set at the beginning.

DR. LOTZ: Well, I guess what I'm thinking is -- and I don't know how epidemiologists do this. But one of the things that, you know, is -- you're going to lose some subjects --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- drop out, certainly if it's prospective. But that if -- so that in a sense, the changing technology is another complication that is another way of losing subjects to the particular group of greatest interest. That's I guess what I'm trying to --

DR. OWEN: Or -- I'm not sure if I'm seeing the same thing or a different facet of the same thing in my mind. But you've got right now -- earlier we were talking about people that become sort of the peak-exposed population, people that are, say, you know, using a phone without a hands-free device, and they're using it for scores of minutes a day or ever how much.

But then with the change in the technology, either with hands-free devices or through more testing or, you know, PTT-type functions or anything like that, suddenly, it was really just a peak of high exposure in minutes. It's gone. How does that affect your -- say you have a large perspective cohort study. How does that affect your power to find anything that was associated with an RF exposure?

DR. KHEIFETS: It diminishes it. I mean,

obviously you have that problem no matter --

DR. OWEN: Or how much, I guess --

DR. KHEIFETS: -- no matter what you do. I mean, it -- it either just sort of diminishes it because

exposure went away, or you're introducing other exposures which could be even more complex.

DR. OWEN: Yeah.

DR. KHEIFETS: And since we don't know whether we care about exposure early on or, you know, later on, or, you know. We have to pay attention. I mean, the possibilities are really endless. That's kind of -- it always --

DR. OWEN: I agree --

DR. KHEIFETS: -- is a problem with all of this, I mean --

DR. LOTZ: Yeah.

DR. OWEN: In having these kind of thoughts, I recently thought of kind of a ridiculous situation really. But you could -- you can envision setting up -- you know, for some reason you were very flush, and you set up a huge prospective cohort study that was supposed to study this particular exposure. And then five years down the road, you found out that basically people were not getting RF exposures beyond what we get right now from base stations, you know, slightly different. I mean, if you just look at it in terms of SARs. What would you do then?

DR. BOWMAN: Well, that's where --

25 DR. KHEIFETS: Just analyze it with the

exposure that they got. I mean, that's --

DR. BOWMAN: I mean, you wouldn't start a prospective cohort study without evidence, which I think is there, that people in their everyday use are getting substantial RF exposures from the cell phones. That's the way -- reason we're starting.

I have never done that calculation myself. I'm interested in doing some trial calculations with the Interphone data. But, you know, just on the basis of the published SARs and their relationship to the guidelines, people that are using the phones at full power, which, of course, doesn't happen very often, are getting a substantial exposure. So that's why we're starting the study in the first place.

How you summarize that exposure over the period of time that you're observing the cohort, like Leeka said, you can come up with all kinds of scenarios to do that. The thing that you start out with is that you have cumulative exposure without worrying whether it's early, late, you know, whether it happens all in one slug or whether it's happening constantly. You just get the cumulative exposure. And that's where everybody sort of starts.

And you can slice and dice that in

25 different ways. But that is your -- the -- the cumulative

exposure is your starting hypothesis that you check out. If there is a confounding exposure, say from work, say from another RF emitter, or from other causes of that cancer, like an ionizing radiation exposure, there you have to assess it and put it into your analysis as a potential confounder or effect modifier and see if it changes your -- your association with the phone exposure.

And you know, that obviously is -- takes a lot of work. And a questionnaire like this is collecting a lot of potentially confounding exposures. And all those have to be looked at both singly and in combination with the cell phone exposure.

DR. KACZMAREK: It does raise an important issue regarding any cohort study. Basically cohort studies have trouble with efficiency when the outcome of interest is relatively rare. And that's relatively true in many of the outcomes that we're looking at. For example, the latest SEER data regarding the incidents of brain cancer in the U.S., is that the age-adjusted rate is only 5.8 per hundred thousand.

Now, certainly, a calculation of acceptable sample size is well beyond the scope of this morning's discussion. But I think it's of interest that the two cohorts that were assembled basically had cohorts

in the hundreds of thousands. That would be Rothman and

Johansen. I think Johansen's cohort was 420,000.

So in the context of a cohort study, it's certainly more realistic to think of a cohort in the hundreds of thousands, as opposed to a cohort in the hundreds.

DR. BOWMAN: In getting that large a cohort in the U.S., how did Rothman assemble -- define his cohort?

DR. KACZMAREK: Billing records.

DR. BOWMAN: Billing records.

DR. KHEIFETS: Yeah.

DR. OWEN: So he didn't have to -- and that was, again, the whole problem was then that they raised this, whether you think it's valid or not, this privacy issue. Because, right, they were assembled without being contacted.

DR. LOTZ: Right.

DR. OWEN: They were just pulled.

DR. KACZMAREK: A comment on case control studies. They have an advantage because the efficiency of a case control study is not dependent upon the rarity of the disease. All the cases have the disease of interest. It's really dependent upon the prevalence of the exposure.

And because of the incredible increase in

the use of mobile phones, obviously, that exposure is no

longer rare. So that's really eliminated a major obstacle in terms of the content -- the convect of case control studies, as opposed to the situation ten years ago. Where if you did the case control study, the use of mobile phones in the study population would be relatively rare. And it really decreased the power of that study. Today it's certainly a very common exposure.

DR. KHEIFETS: So the childhood brain tumors is like two per hundred thousand, or something? What's the rate for childhood --

DR. KACZMAREK: The rate for children. Okay. Actually, I have some age specific rates in front of me. From zero to four, it's 3.8 per hundred thousand. Five to nine, 3; and ten to fourteen, 2.7. And I think fifteen to nineteen is 1.9.

DR. KHEIFETS: So it's about three. So it's not that much rare -- more rare than adults, about half of what the adult is. But --

DR. BOWMAN: The disadvantage of case control studies in the U.S. is selecting the controls.

That -- random digit dialing is one common method used. And that is known to have biases because of changes over demographics as to who has listed -- you don't -- it doesn't require a listed phone number. The phone numbers are generally at random. But who answers the phone.

DR. KHEIFETS: Well, maybe with cellular phone system it'd be different. You just call their cell phone.

DR. BOWMAN: Right. Good idea. But, in any case, that has certainly been an issue with case control studies in the U.S., is questions about the representing those controls.

With cohort studies, a problem in the U.S. is, do you follow up the outcomes with death certificates, which does raise an issue of the survival rate between the onset of the cancer and -- and the death.

With brain tumors themselves, that's not as much a problem as with some other ones. But you still have a less perfect look at the etiology of incidents. And then in the U.S., to get incidents, you need tumor registries. And there's not a hundred percent coverage of the population in that way. There's localities that have tumor registries, but there's plenty of localities where there aren't.

DR. KACZMAREK: Certainly the use of death certificates raises questions. A lot of times that information is incomplete. You may be certain that the patient died. But the primary cause -- the actual underlying cause of death may not really appear on the death certificate.

DR. OWEN: One thing I haven't heard yet mentioned, so I'll bring it up. And this goes back to the goal of why we're collecting information through this meeting. And it again is to ask questions about what kind of follow-up is needed from the Muscat Study.

And I don't think anybody mentioned that that study did have a positive result in a sub-group tumor type. And so that's certainly the reason that that study was identified by its funders as a study that they wanted to know whether follow-up is required, because it was viewed as a positive study.

Now, granted, many people, particularly people that are fully informed in the details of the kind of work may not be comfortable with characterizing that study as a positive study on the whole. But, nonetheless, that was the -- sort of the motivation for the CTIA identifying it as one they wanted to know how they should follow that up.

So does -- does that, and, if so, how does that give anybody ideas about the kind of follow-up that

might be needed?

DR. KACZMAREK: There's a question regarding that study, the form -- whether that result itself reflects the performance of multiple comparisons. That is, they looked at numerous sub-types of glioma and

basically found, you know, found one that was positive.

But when you look at -- when you do multiple comparisons of the same data sample, there's a potential that what you find may actually only represent a chance finding.

So what there's a real need for is to replicate that study and to look in other studies and to have them look at the same sub-types of tumors to see whether that finding is a chance finding or an actual finding. So I think in terms of follow-up, that's probably an important place to go.

Although it probably raises an even larger issue, that brain cancer, per se, is not just one cancer. There are numerous types. You have meningiomas. You have gliomas, acoustic neuromas. And I think it's very important, particularly within the context of case control studies, to mount studies to look at those particular major categories of types of tumors and not just look at brain cancer in the aggregate, because they -- the tumors arise from different places.

DR. BOWMAN: And that's one area where better exposure assessment would help our outcomes, is that the depositions of energy from the cell phone is really localized. And the better dosimeter phones, the Motorola phone that actually has -- you know, records

information as to which side of the head the phone is held on and how the antenna's held, at least in the absent spacial sense, if not relative to the head. That that information can then be correlated with location of the tumor.

And there's been efforts to do that in all the studies up to now. And so far they haven't shown anything. But like we've been saying, the exposure assessment isn't that definitive either. So, I mean, you're really looking at comparing --

DR. KHEIFETS: Does anybody have a copy of the paper, the Muscat paper?

DR. OWEN: What, the Muscat Study?

DR. KHEIFETS: Yeah.

DR. OWEN: No, I don't. But in -- and I don't know if this is where you were going. But since Pete's -- since Peter Inskip's not here, I'll just point out that at the meeting a couple weeks ago, you know, he, obviously, his study had the potential for being an unintentional replication of the Muscat Study in certain

ways.

And he -- he certainly did not make a case for the sub-group finding of the Muscat Study being a -- something that he felt either required -- merited, you know, a replication in particular, but he also pointed out

within -- with several caveats, of course, that, you know, the finding didn't pop up in the Inskip Study. You might want to add to --

DR. LOTZ: Yeah, I --

DR. OWEN: -- what he said on that.

DR. LOTZ: I think my recollection --

DR. OWEN: But he clearly said it wasn't designed for that.

DR. LOTZ: -- my recollection was, to some extent, falling upon what Ron said a little bit. That Peter was saying that -- and I don't recall whether it was specific. But they had also looked at -- done some looking at sub-types.

And he felt within the two studies, that if you looked at them together, that his study was very much negative, at least in the same types of brain tumors. I don't remember whether they did exactly the same breakdown in types.

DR. OWEN: Not quite.

DR. LOTZ: I think it was a little different. But he felt it was close enough that the --

DR. KHEIFETS: Why didn't they do exactly the same?

DR. OWEN: Well, there's not agreement in the pathologists. You know, pathologists done really

agree on this -- the classification. I mean, there -- there are standards. But you get down into really the art and interpretation, that's my understanding of the problem.

DR. KACZMAREK: That was certainly an issue raised with the Muscat Study, whether the pathologic classification was correct.

DR. LOTZ: And so Peter's -- Peter's interpretation was that his study provided as much evidence to say there wasn't an association, as the Muscat Study said there was. And that so in the sense of two -- neither study having very much power in itself, that they kind of washed each other out in every part.

DR. OWEN: I haven't had a chance to talk to Peter again since that last meeting, and we don't have the transcripts in hand yet. But maybe you can help me, you and Abiy, since you were here. I thought that Peter actually made the statement that neither of those studies was really designed for these sub-type or sub-group comparisons. Is that your recollection?

MR. DESTA: Um-hmm, yes.

DR. LOTZ: I think that is.

DR. OWEN: I mean, I know it's for sure the case for the Inskip study. But it wasn't clear to me whether that was the case for the Muscat Study.

DR. LOTZ: He didn't put it in the same context. But, in a way, I think he was sort of going at the same or consistent, certainly, with Ron's comments about, you know, the multiple comparisons and just sort of looking for different possibilities, and that it was -- it was more a, you know, a post-hoc analysis of that --

DR. OWEN: Hypothesis generation.

DR. LOTZ: -- that it was.

DR. KHEIFETS: Did he talk about what was the sort of minimal detectable risk from his study? I mean, do you know, was it a negative study?

DR. LOTZ: Well, he -- he didn't --

DR. KHEIFETS: Did they do any calculations?

DR. LOTZ: He didn't disagree even with the limitations even that we've talked about --

DR. KHEIFETS: Right.

DR. LOTZ: -- here today.

DR. OWEN: I think he said, or perhaps he even wrote it in the paper, that overall he felt it would

have detected a two-fold. But for a sub-group that it would have had to be something much larger to be detectable, you know, by power calculations. And that's -- and, again, that's why the studies weren't designed to do that --

DR. KHEIFETS: Right.

DR. OWEN: -- because nobody's going to do a -- propose to do a study that requires a, you know, five or ten fold increase in incidents to be detected by the study. I mean, if that were the case, we might not need a study to see it.

DR. LOTZ: Right.

DR. OWEN: I guess again going back to what he said. Someone else asked, I think, whether it might be possible to pool the data from those two studies and sort of do a pool or parallel analysis. I got lost a little in the terminology there.

DR. LOTZ: There were --

DR. OWEN: So actually Ken -- Ken finally volunteered that there wasn't a consistent definition for -- or for the use of those terminology.

DR. LOTZ: There certainly wasn't around the table.

DR. OWEN: Right. But Peter did seem to

agree that at least there was potential for possibly taking the data from those two studies and doing more careful analysis use -- pooling both of those sets of data together to see what was going on.

And I think that's where -- I think that conversation is the one that led to the one that Greg was

remembering about him saying that he, just from his gut, you know, what he knew already, they he thought they were kind of -- would wash out.

DR. LOTZ: Yeah. Yeah, he hadn't -- he hadn't done anything rigorous to demonstrate that.

DR. BOWMAN: Well, that --

DR. LOTZ: But that was his sense of --

DR. BOWMAN: That certainly would be one fairly obvious thing to put on a future research list. And --

DR. KHEIFETS: Well, certainly IARC could test that particular --

DR. BOWMAN: -- hypothesis.

DR. KHEIFETS: -- I mean, I think in advance, that particular sub-type. I mean, that's -- they don't have to search for a --

DR. LOTZ: Yeah.

DR. BOWMAN: What's the sub-type that turned up in the Muscat Study?

DR. KACZMAREK: Neuroepitheliomatous tumors.

DR. BOWMAN: And that is --

DR. KACZMAREK: Some type of gliomas.

DR. BOWMAN: And located where?

DR. OWEN: Peter said that they are

temporal, but not peripheral. Which would be -- and, of course, he was trying to make the point that that would maybe not be consistent with an association with the exclusion --

DR. BOWMAN: What -- what's that mean? Temporal lobe, but --

DR. OWEN: -- but not --

DR. BOWMAN: -- on the periphery.

DR. OWEN: -- on the periphery.

DR. LOTZ: Well, I thought -- I thought he said they were not -- there had been some sort of, I think the lay commentaries --

DR. OWEN: Yeah.

DR. LOTZ: -- that have suggested that they would be -- where they would be peripheral, therefore being in the exposure area of greatest interest. I thought Peter's comment was that they were more distributed and not --

DR. OWEN: Yeah. I'm sorry. Not --

DR. LOTZ: So it wouldn't -- that they wouldn't occur peripherally --

DR. OWEN: But not exclusively peripherally.

DR. LOTZ: -- but they wouldn't

preferentially occur.

DR. OWEN: Or preferentially, yeah.

DR. KHEIFETS: And there was a hint of hand incidents in this Muscat data? I can't -- I'm trying to remember.

DR. LOTZ: No, it's the Hardell Study that studies the --

DR. KHEIFETS: It's only Hardell.

DR. OWEN: I think it's only Hardell.

DR. KHEIFETS: I think there is one more.

DR. KACZMAREK: No. With Muscat, the relationship was not statistically significant. But there was --

DR. LOTZ: Oh, there was a --

DR. KHEIFETS: -- some sort of relationship.

DR. LOTZ: Okay.

DR. KACZMAREK: Also, in the context of the Inskip Study, there's no statistically significant association between handheld cell phone laterality and the relative risk of either glioma, astrocytic glioma, meningioma or acoustic neuroma.

DR. LOTZ: So --

DR. KHEIFETS: But there is non-statistical significant result --

DR. KACZMAREK: Right, no statistically

significant association.

DR. KHEIFETS: But there is an association that's not statistically significant?

DR. KACZMAREK: I don't recall the numbers offhand. But it's certainly not statistically significant.

DR. KHEIFETS: Um-hmm.

DR. KHEIFETS: I'm not even sure it's more than one.

DR. OWEN: But based, at least for the neuroepitheliomatous sub-grouping -- and, actually, Peter also made a point of he did well a little bit on the fact that there was this inconsistency in various people's applications. I think I provoked it by -- I was calling it sub-type. And when I called -- when I referred to it as a sub-type, he actually pointed out that it was nothing nearly so well-defined as a sub-type, but rather a sub-grouping.

And it almost seemed like he was saying it was kind of a very loose grouping. And that was part of the reason that there was inconsistencies in the way various tumors are group.

DR. KACZMAREK: Well, certainly,

overall,

24 within the context of the Muscat Study, there's no

25 association between mobile phone use and brain cancer in

the aggregate. I mean, the multi-variate odds ratio is less than one. It's 0.85. And there's no statistically significant association between primary brain cancer and the study in either the years of mobile phone use, the number of hours of use or even the cumulative number of hours of use. So, certainly, in the aggregate, there's a lot of evidence against an association.

But there was an important limitation in the study, that the mean duration of use is only 2.8 years for the cases and 2.7 years for the controls.

DR. KHEIFETS: It's -- in the Inskip Study, most of the risks is way below one, actually.

DR. KACZMAREK: Right.

DR. KHEIFETS: Except for acoustic neuromas which are kind of different for some reason.

DR. OWEN: And Muscat hasn't reported the acoustic neuroma portion of their studies yet. Or hasn't published, I should say.

DR. LOTZ: So they have data on that, but that's what -- I know it wasn't part of the publication --

DR. OWEN: It wasn't in the December paper.

DR. LOTZ: -- so far. But --

DR. OWEN: Yeah. He's described it in --

25 I think in the colloquium in '99, in LA, as -- as I

recall, as being all negative.

DR. LOTZ: I was going to say, I didn't remember there being any attention drawn to that.

DR. OWEN: Yeah.

DR. LOTZ: Which, given, Carlo's propensity to draw whatever he can out of it, I would think I'd have heard about it.

DR. OWEN: Yeah. Yeah. I just wanted -- you know, it hasn't been published in this kind of detail yet. And so we don't -- we can't look at Muscat's acoustic neuroma results the way we can Inskip's.

DR. KHEIFETS: Did Inskip sort of comment why his ratios are so low? I mean, it's just really strange, actually. I mean, he has a significantly reduced -- I mean, I don't care about significance that much. But he has a significant -- for those who do -- there is, I mean, statistically significantly reduced for all brain tumors. The area of use began to close 1990. There's a statistically significant reduction.

So it seems like there is some sort of

bias --

DR. OWEN: I don't recall --

DR. KHEIFETS: -- to this inference. I mean, it's very consistent.

DR. LOTZ: Actually, I don't think --

DR. OWEN: He didn't say anything about SES findings.

DR. LOTZ: -- anyone asked that question, and he didn't bring it up himself either as something --

DR. KHEIFETS: Uh-huh, that he did --

DR. LOTZ: -- notable --

DR. KHEIFETS: Right.

DR. LOTZ: -- or that he was particularly interested in. He just didn't --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: I don't recall him bringing it up.

DR. OWEN: I think there was mention of a socioeconomic effect in the Johansen Study. Is that right, Ron?

DR. KACZMAREK: Yes. And what you're raising is another important point, that certainly in the context in the overall mortality, you have to adjust -- well, you should adjust for socioeconomic status --

DR. OWEN: Right.

DR. KACZMAREK: -- in any case. But certainly, if you look at overall mortality, a higher socioeconomic status definitely is associated with lower overall mortality rates. And that's certainly true for two reasons. The first of -- first reason is that

individuals of higher socioeconomic status have better access to the medical care system.

And, secondly, they tend to have better health habits. For example, there's an inverse association between cigarette smoking and socioeconomic status.

So I think that Johansen did not adjust his results for socioeconomic status, and he found an overall lower mortality rate among the cellular telephone subscribers. And I think there's a clear need in future studies to adjust for socioeconomic status.

And, in fact, in the context of the Inskip Study, Inskip did find a very clear association between handheld cell phone use and household income and educational status, which are quite useful markers of socioeconomic status. He saw it unreasonable to think that cell phone users are of higher socioeconomic status than the general population.

So that's, again, something that future studies should definitely address.

DR. BOWMAN: In what way?

DR. KACZMAREK: I think if you're going to

look at overall mortality rates, you may view that in the context of a cohort study. You'd need to make adjustments for socioeconomic status. I think there's -- again,

Inskip found that association that the mobile phone users are a part of socio -- there was an association between mobile phone use and higher socioeconomic status.

DR. BOWMAN: Oh.

DR. KACZMAREK: Socioeconomic status is associated with lower mortality rates.

DR. BOWMAN: Right.

DR. KACZMAREK: So you need to make that adjustment in terms of your analysis of the data.

DR. BOWMAN: Okay.

DR. KACZMAREK: You're just going to look at overall mortality rates among mobile phone users.

DR. BOWMAN: Right.

DR. LOTZ: Ron, to take that a step further --

DR. KHEIFETS: Overall brain --

DR. LOTZ: I was going to say --

DR. KHEIFETS: I mean, with brain cancer, yeah, it's true as well.

DR. KACZMAREK: Yeah.

DR. LOTZ: Is it also -- does it go the same way?

DR. KHEIFETS: Yeah, it's --

DR. LOTZ: Cause I was thinking it was one

25 --

DR. KHEIFETS: Well, it's a higher -- for brain cancer, it's a higher --

DR. LOTZ: It's actually reversed, isn't it?

DR. KACZMAREK: It goes the -- it goes the other direction, that's correct.

DR. KHEIFETS: Right, it's a higher.

DR. KACZMAREK: Brain cancer is actually associated with higher socioeconomic status.

DR. KHEIFETS: Right.

DR. KACZMAREK: Overall mortality rates are inversely associated with socioeconomic status; that is, the higher your status, the lower your overall mortality rate.

DR. OWEN: Do any of these things bear at all --

DR. KACZMAREK: So there are -- there are certain diseases that we should note for the record where if you're a higher socioeconomic status, you're actually at a higher risk, although, overall, you're at lower risk in terms of all -- all cause mortality.

DR. OWEN: Does any of this speak to the question that you raised, Leeka, about the large number of very low odds ratios?

DR. KHEIFETS: Well, I -- I can't recall.

But I assume he adjusted for ACS in his analysis.

DR. OWEN: Okay. So --

DR. KHEIFETS: I mean, we can look in that table. So that might be partial explanation, but -- they were adjusted for age, sex, race, hospital, distance from patient's residence, education, so on, so on. Self-reported -- so they adjust for all of that.

DR. KACZMAREK: Just a comment. He didn't study patient -- or patients with neomas, patients with meningiomas and patients with acoustic neuromas. That is three separate types of tumors.

And the upper limit of the confidence interval is above one. I mean, it's not a statistically significant decrease in all of the cases. I mean, for glioma, the relative risk, was one. But the 95 percent competence interval went from 0.7 to 1.4. So it's not a statistically significant decrease. For meningiomas, the relative risk was 0.8, with a 95 percent competence interval running from 0.5 to 1.2, again more than one.

DR. KHEIFETS: Well, there was one that was below -- there was one interval that was below one. But I was just commenting on the overall pattern, more than any statistical significance. There is -- there is just one that's statistically significant below one.

DR. OWEN: In this --

DR. KHEIFETS: In this table.

DR. OWEN: Right. And this -- this might suggest the possibility of particular sorts of bias.

DR. KHEIFETS: I mean, I would certainly try to understand why, you know, this pattern occurred. I mean, they are -- they're all -- they're not that far from one; some are. But, you know, it just -- I think it looks kind of funny. I don't know, something going on that would be good to understand, I mean, maybe.

DR. KACZMAREK: It might be a question to pose to Inskip to get his thoughts regarding this.

DR. OWEN: Yeah. Yeah.

DR. LOTZ: Put that in context with the Ross-80 Study and you have evidence for protective effect, right?

DR. OWEN: Let's take a few minutes break here, and try and start -- I've got 17 of right now. Let's try to start back up at ten.

DR. LOTZ: Okay.

(BREAK - 9:44 to 10:12)

DR. OWEN: Brian will have to catch up. I thought we'd catch him there at the break.

What I thought -- what I wanted to

suggest
as a starting point for the discussion now was to see about getting into more detail about what kind of exposure

assessment needs there are, both for, you know, for either cohort or case control studies. I mean, we've talked -- it was mentioned a fair amount earlier. But I was wondering if we could just get out on the table some ideas that are even more specific of the kind of things that are needed.

Perhaps a starting point is where the Interphone Study from IARC, coordinated by IARC, leaves off. Cause that's a -- that's an important function here. And I don't think I used these words yet this morning. But the, you know, the process here is to identify data gaps in the kind of studies that might close those gaps. And it's our intention to include not only published studies, of course, but anything we know about things that are going on already.

And the reason for that is probably pretty obvious. But there's basically two reasons. One is, you don't want, you know, unnecessary duplication or things to, you know, new things to start where somebody else is already, you know, down the road, trying to solve that problem.

And the other is, as I mentioned, maybe not in the meeting, but at least in sidebar discussion, we have a -- we, FDA, have a vested interest in making sure

that work gets prioritized to increase the likelihood that

it will get done.

And so I want to be able to have as much detail available as possible when it comes to the difficult task of actually drawing together recommendations to give to CTIA for the kind of work that they might do.

DR. KHEIFETS: Can I ask a question? We've been focusing on the cell phone users. Are occupational exposures of interest to -- or part of this deal? Or is this really we're focusing on a specific aspect of --

DR. OWEN: I would be happy to talk about that. And I will bring back up again the request for details on exposure assessment. And when Brian gets here, of course, he's going to be a critical part of that discussion.

The -- the goal here, again, is to follow up or to see what kind of follow-up is needed for the Muscat Study. But all epi studies having to do with RF are within the scope of discussions here and are important to consider in terms of coming up with overall recommendations.

I would like to talk a little bit about occupational users, not only because of, you know, FDA's

interest is not, in general, restricted to wireless phone

exposures. But also because it's reasonable to think that occupational users would -- you know, could be a population to study for -- for wireless phone issues as well. So go for it.

DR. BOWMAN: There you go.

DR. KHEIFETS: Well, it just seemed to me that there hasn't been an emphasis on occupational exposures from RF that could be -- I mean, there is one study by Morgan of Motorola employees that really, you know, again is very week in terms of the exposure assessment.

And there hasn't been too many studies. I mean, the studies that are there, I mean, there are -- I guess there are a number of studies, if you really look at it very broadly, in terms of radio operators and all -- all kinds of stuff like that, that are usually considered within the ELF literature as well.

But there aren't any really next generation, what I would call sort of next generation studies that have been done in other areas, and -- in

terms of exposure assessment.

DR. BOWMAN: Right.

DR. KHEIFETS: So -- and it seems to me like sort of nobody's paying attention to that aspect particularly. I'm sorry, I shouldn't say that. I mean,

you know, we're not paying enough attention to that aspect, because -- I mean, in addition to all of the people starting to use phones, there are a lot of -- a lot of antennas and equipment that's being thrown around on all kinds of -- in all kinds of places.

And, potentially, there are a lot of people who are getting occupational exposures who work in the vicinity, intentionally or unintentionally. You know, both people who are servicing the antennas in particular, maybe they're always turned off; I -- I don't think they are, but -- and then there are those who are not working on antennas, but, you know, fixing something else nearby. And I'm pretty sure then, a lot of times, antennas are not turned off.

So, I mean, I think those are the two kind of --

DR. LOTZ: We've, within our little group at NIOSH, we've talked a lot about some of these people and actually done a fair amount of work to try and better measure their exposures when we come across them.

The harder question, in terms of actually an epidemiologic study is trying to put together a sizeable enough group of them and just find them. I think one of the historical things with -- is that the wireless telecommunications revolution, if you will, has changed,

is that RF exposure used to be limited to very specific occupational groups who weren't necessarily easy to get to collect.

DR. KHEIFETS: It was mostly military, right?

DR. LOTZ: Well, you had some significant --

DR. BOWMAN: That was --

DR. LOTZ: That was the biggest group for sure, and still probably represents both the biggest and maybe the most accessible in terms of finding them. They're -- they're all sort of in one system, one employer almost. There's been various other industrial sources that we know represent strong RF exposures, sometimes even in excess of the guidelines, like industrial heater and sealer users, people like that. But they tend to be scattered. And there -- there's substantial numbers of those, at least in the United States nationally. But they're scattered around in small businesses.

DR. KHEIFETS: There was one study of them, right?

DR. LOTZ: Yeah, there's been --

DR. KHEIFETS: Who --

DR. LOTZ: Well, Barb Grajewski actually

did a study looking at reproductive issues in males.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: But they ran into problems getting enough subjects, even the cooperation of the sites themselves.

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: So there's been some problems that way. And then the people who work around the towers are a definite, you know, sort of obvious in the -- to the sense of people being exposed. But, again, difficult to corral --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: -- substantial numbers of those people. So I think that's been the dilemma. And even in the World Health piece that Russ passed out to us before the meeting, and I was a part of that discussion where that was first talked about anyway, the idea that those -- or occupational populations would be valuable to study because their exposures might be stronger in general and, therefore represent a greater --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: -- chance of detecting out comes. But it's -- we seem to be stuck on the problem of identifying the population and being able to actually

track it. Or at least a sizeable enough group. So that's -- that's been kind of the dilemma.

Military members may, in fact, represent the most accessible group in that respect.

DR. BOWMAN: The -- both the Interphone Study and also NCI's Study, which I believe is the Inskip population, in their interview did -- in their interviews on both cases did ask about broader occupational, both RF and power frequency EMF exposures.

And let's see. Just to read through -- this is the computerized questionnaire, as opposed to the paper version. So they start out asking about industrial heating equipment, both radio frequency and -- and ELF. And including in that is welding, both metal welding -- or metal welding, which is ELF, for the most part. There's some ELF from induction heating. But also welding of plastics, which is an RF function.

And they break that out by materials. So there's plastics, woods and other laminates, fiberglass, ceramics, semi-conductors, nylons. And then they go on to heating and food processing and -- and this is quite detailed. And this, by the way, does come after looking at other communication devices, walkee-talkees, both personal and occupational, amateur radio operators. So this is all after the more obvious kinds of radio frequency communication devices are -- are gone through.

So this is, you know, broad occupational

exposures. And then it goes on to radar, both repair and -- and use, medical devices. And it brings in MRIs, which is both a low RF, but also a very strong static magnetic field. Electric motors, which is an ELF exposure. Electric transport, which is primarily ELF, but also some static. Airline pilots and crew.

There's a fair amount of data on a lot of these from ancillary exposure assessment. So in all these cases, of course, it's known broadly that they're exposed. But also, if you go back over the past couple decades, there's often exposure measurements taken in -- in a lot of these things.

Electric utilities, construction repair testing and maintenance, electrical equipment and other electrical work.

So that's the -- that's the kinds of occupational exposures the uniform study covers.

DR. KHEIFETS: Do you guys know what happens when -- I mean, there are people who service the antennas? Is there -- I mean --

DR. LOTZ: There are a few anecdotal cases of some severe --

DR. KHEIFETS: Some burns.

DR. LOTZ: -- injury.

DR. KHEIFETS: Yeah.

DR. LOTZ: Yeah. But --

DR. KHEIFETS: But so do they turn them off when they service them always?

DR. LOTZ: Not necessarily.

DR. KHEIFETS: Not necessarily.

DR. LOTZ: A lot of the major broadcasters will have an alternate antenna, like a radio station or whatever. So they might be actually turning it off. But in some cases where -- particularly some of the ones, I think in cities on tops of buildings, where they really don't have. Or what typically has happened, I think, generally, with the more severe anecdotal accidents, is that somebody thought it was turned off and it wasn't.

But the other problem is that now we have -- there is so much proliferation of multiple antennas at the same site.

DR. KHEIFETS: That's what I was going to say, there are these antenna farms.

DR. LOTZ: Yeah.

DR. KHEIFETS: I'm sure they don't turn all of them off. They just turn --

DR. LOTZ: Well, that's common on buildings. You know, you get a building where it's in a key location and has, you know, the highest roof around or

whatever. I mean, you can go in any -- any city of any

size, even -- we recently went on a rooftop, it was a ten-story building in Springfield, Ohio. Springfield, Ohio's a, you know, a very -- it's a city, but it's a small city. And the ten-story building was the tallest one in town. And it just had lots of different antennas on it.

But -- so generally then, they're not -- you know, the one they're working on might be turned off, but none of the others are.

DR. KHEIFETS: So it seems like that's --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- you know, a possible cohort is -- is the people who do that kind of work.

DR. BOWMAN: But all of what Greg said earlier applies here, is that maintenance of this is diffuse over a large number of companies. So to get a large enough cohort, you have to, you know --

DR. KHEIFETS: Are -- are there a lot of -- are there any main -- big companies that have a lot of workers?

DR. LOTZ: We've been in touch with -- there's an organization called the National Association of Tower Erectors, NATE, that has several hundred members that tend to be the companies who own the sites or operate them.

But based on what we can find from them,

they're not dealing with any major employer of tower maintenance people. They're dealing with local contractors, you know --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- a few here, few there, all over the place. And so that's why I say, it seems to be a really hard population to get a handle on and actually track.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: And these -- I don't know. These guys tend to be pretty -- sort of the rugged type. They're not -- I mean, a lot of them are climbing hundreds of feet. And you've got to be pretty rugged to do that. So that they're -- they're not that interested in being part of a study or seems to be.

So it does appear to be a formidable obstacle to a good study, even though you've got -- the other population that with the proliferation of rooftop mounts are, and I think you kind of referred to these people, is the people who are up there to repair other

things or work on other equipment, air conditioning equipment --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- all the kinds of things that get put on rooftops.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: But again, those are all just your local, you know, electrical heating and air conditioning contractor. And there's not a systematic collection of them to track.

DR. KHEIFETS: Are there, in Europe or somewhere in the world, is there more --

DR. LOTZ: Now, that I don't know whether --

DR. KHEIFETS: -- consistent --

DR. LOTZ: -- whether there's more systematic --

DR. KHEIFETS: -- systematic --

DR. LOTZ: I know that in Europe, they're -- at least they used to be. I think they still are. They're a little better organized in terms of the coordination of tower construction. In other words, they tend to co-locate things and -- and have more systematic control, as opposed to every company putting up their own towers, that type.

DR. BOWMAN: Has the WHO and the national EMF project done a, you know, a systematic coordination or collection of what studies are going on, like had gone on in the past with ELF?

DR. LOTZ: You mean just collecting

information on who studied what?

DR. BOWMAN: Oh, just what studies. I mean, I remember --

DR. OWEN: Yeah, they have --

DR. BOWMAN: -- that during the rapid program, there'd be annual meetings where everybody that was doing studies would get together and they --

DR. KHEIFETS: They're trying to put a lot of this stuff on the web site to --

DR. OWEN: It's not comprehensive.

DR. KHEIFETS: Absolutely not.

DR. OWEN: It's far from --

DR. LOTZ: There's been some effort to do that, but it hasn't been very --

DR. BOWMAN: I would certainly try and dig out that U.K. Study. And I can correspond with the NRPB --

DR. KHEIFETS: Yeah, what are they doing? That's an occupational study, you said, right?

DR. BOWMAN: Yeah.

DR. KHEIFETS: So that would be an interesting --

DR. LOTZ: That would be, cause --

DR. KHEIFETS: Yeah.

DR. BOWMAN: My vague recollection is that

people are -- the university leads, some of the people that were involved in the Harrington Study also were doing that.

DR. KHEIFETS: Yeah. In fact, Alister did tell me that they actually going to use the meters that they developed. Now it's all coming back to me --

DR. BOWMAN: Say that again.

DR. KHEIFETS: -- in small pieces.

DR. BOWMAN: What --

DR. KHEIFETS: I talked to --

DR. BOWMAN: Alister Woodsonow?

DR. KHEIFETS: No.

DR. OWEN: McKinley.

DR. KHEIFETS: Alister McKinley.

DR. BOWMAN: Oh, okay.

DR. KHEIFETS: I was talking to him about meters. And he said that they have developed some sort of meter for RF exposures that they're going to use in the occupational study.

DR. LOTZ: I think that Stewart Allen mentioned that in the meeting in San Antonio, I think, last October.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: And I did talk to him a little

bit about it, but not -- not a lot, you know, not in any

detail. And I haven't corresponded with him since.

DR. KHEIFETS: I might have some information on that in my email. I'll check tonight if I could dig out any information, if I still have it. But there might be something.

Yeah. So there is -- and probably that's the same --

DR. BOWMAN: Yeah.

DR. KHEIFETS: -- U.K. study, right?

DR. BOWMAN: That's the only one I've heard of that's in the pipeline, that --

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: -- is looking at occupational exposures beyond the questionnaire mode.

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: The only -- the other -- the people who probably, at least considered the occupational arena the most in RF, although I don't know if they have anything new going on, are the Swedes, Monica Sanstrum and Sheryl Mill.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: Because they specifically structured one study to look at people who were required to use mobile phones on their job. They had about

12,000.

Actually, they collaborated with the Norwegians with a

survey instrument to look at rather non-specific symptoms like headache, pain in the skin, things like that.

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: And they've published one report on that, and I know are still working -- they've been working on some things, like going back and looking at the SAR distribution from the phone in question, which would have been identified in the survey, and things like that.

Now, I don't know if they've gone on to -- but they've done more to track RF exposed people in an occupational sense -- and I mention that it's mobile phones. -- but in other occupational areas too. Medical uses like diathermy or physical therapy --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- those kinds of uses.

DR. BOWMAN: And my experience with the Swedes is, once they've identified a study population, they usually, you know, go back and --

DR. LOTZ: Yeah.

DR. BOWMAN: -- dig for all it's worth.

DR. OWEN: My recollection of the --

of

the study you were talking about, was that it was exclusively using questionnaires, right?

DR. LOTZ: It was.

DR. OWEN: Yeah.

DR. BOWMAN: But again, once you get a study population, in Sweden there is --

DR. OWEN: Well, to --

DR. BOWMAN: -- with a national health system, it's easy to then make it to rule out industries, of whatever.

DR. LOTZ: Right.

DR. OWEN: And they're on Interphone.

DR. BOWMAN: Once you get the approvals, of course.

DR. LOTZ: And that may be in the case of the -- the cancer aspect, they may have -- be putting their energy more into being a part of Interphone at this point, in terms of --

DR. BOWMAN: And they are. I mean, they are one of the component nations in Interphone. I think they might even be the lead investigator.

DR. LOTZ: Right.

(ENTER BRIAN BEARD - 10:33)

DR. KHEIFETS: Are there enough people, sort of in the general population, with those kind of jobs that one might consider it a two-stage design, so you do sort of a population case control study and then within

you only include a sample of certain people with certain

jobs, to capture those kind of jobs?

DR. BOWMAN: But wouldn't that dilute your -- by the time -- if you do a population-wide case control study with a rare cancer like brain cancer, and then you narrow it down just to people in particular jobs, would that -- wouldn't that be a fairly small number of --

DR. KHEIFETS: Yeah. But, I mean, you just sample it to just certain jobs, you know, jobs that you think -- you do a two-stage sampling. You sample both. You know, you're sampling jobs that you think are high exposure at sampling jobs that you think are low exposure.

DR. LOTZ: You know, in --

DR. BOWMAN: Well, certainly, I'm a big fan of two-stage designs, as far as the opportunity for exposure assessment is concerned.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: My only question is, is the numbers don't justify the --

DR. LOTZ: Yeah. I think when you start talking, okay, how many people out there in industrial situations are using strong RF emitters like, you know, plastic welding and that kind of thing. The information that we have, which is pretty crude, suggests there might

25 be several hundred thousand of those people. But when you

start looking at that as a proportion of a population that you've got otherwise --

DR. KHEIFETS: But it would include much broader, all those people who work on top of the roofs and --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- you know. I mean, again, you -- you have it as a first cut.

DR. LOTZ: Part -- yeah.

DR. KHEIFETS: Then you do a full up with the case control design.

DR. LOTZ: That --

DR. KHEIFETS: It's a just a way to try to capture that diffuse population.

DR. LOTZ: Yeah. I don't know whether -- whether there's enough of them to emerge out of a, you know, a two-stage design like that or not. It's worth pondering.

And one of the things that certainly has been, I think kind of emphasized to me, is, we could afford -- it would be valuable for us to spend maybe some concerted effort to try and get a better awareness of what those populations are like. Where are they? Who are they? How many are they?

DR. KHEIFETS: Yeah.

DR. LOTZ: Cause all that information is very vague at the best, at this point.

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. BOWMAN: Maybe something like the Brigitta Fleurduras' original ELF design, where you do a population-based case control study. And then to the extent feasible, go to the company and -- and find a surrogate in -- in the job --

DR. KHEIFETS: Um-hmm. Um-hmm. Um-hmm.

DR. BOWMAN: -- that the person was performing.

DR. KHEIFETS: Yeah. I was trying to make it a little bit more efficient. But, yeah, you could do something like that too.

DR. BOWMAN: Well, that's obviously a very labor-intensive thing.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: And even in the case of ELF, it was going so slow, that she had to change course in mid-stream and make it more a job exposure matrix kind of thing.

DR. KHEIFETS: Yeah. But look how many times that -- that job exposure matrix has been used over and over and over again.

25 DR. BOWMAN: Oh, and it's certainly --

DR. KHEIFETS: So it seems like a --

DR. BOWMAN: -- been very effective. But -- DR. LOTZ: Do you suppose we could use that --

DR. KHEIFETS: Use that matrix for this?

DR. LOTZ: No. To build a rationale for, you know, even NIOSH, you ought to fund the study, cause look how many times it might get used down the road.

DR. BOWMAN: Well, the other way around --

DR. KHEIFETS: I don't know if it's a plus or a minus.

DR. BOWMAN: -- it, of course, is to use some kind of population-based survey to identify RF exposures and then just go out and measure exposures in --

DR. KHEIFETS: Yeah.

DR. BOWMAN: -- in those jobs, rather than trying to focus on the cases and controls --

DR. KHEIFETS: Yeah, sure.

DR. BOWMAN: -- and identifying the disease.

DR. KHEIFETS: Sure.

DR. LOTZ: Yeah, that's probably a good --

DR. KHEIFETS: Yeah, sure.

DR. LOTZ: -- approach. The other side of

the occupational aspect would be to maybe narrow in on the mobile phone users who, in their occupation, use the phone a lot, representing a high-end user group.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: And that's where the Swedish Study is of interest, because you start -- and Motorola's cohort might also be of use there.

DR. LOTZ: Yeah. That would presumably be, you know, sort of --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- the idea behind the Morgan Study, in terms of, okay, these were people -- but --

DR. KHEIFETS: But those were not the people who were using mobile phones. Those people were manufacturing them.

DR. LOTZ: Yeah.

DR. BOWMAN: Right.

DR. LOTZ: Well, they were developing them. Yeah it was --

DR. OWEN: You know, that --

DR. LOTZ: It was developing and manufacturing.

DR. OWEN: It was notably lacking in wireless phone --

DR. LOTZ: Yeah.

DR. OWEN: -- data, it seemed.

DR. LOTZ: Right. Yeah, it was -- it was not specifically tailored toward that really at all.

DR. KHEIFETS: Right.

DR. LOTZ: But in the -- in the case of phone users, probably people like real estate agents and the people who sell mobile phones themselves, which is a sizeable work force now, certainly in the last five to ten years, represent high-end users that probably have, you know, many hundreds of, even thousands of minutes a month.

DR. BOWMAN: Well, certainly, the cell phone service providers not only have, you know, things like sales people and marketing people that use it out of preference, but they also have the repair people --

DR. LOTZ: Um-hmm.

DR. BOWMAN: -- for towers, which -- so if they're --

DR. LOTZ: No, actually, they don't --

DR. BOWMAN: There are the larger corporations.

DR. LOTZ: Well, actually, they don't have the tower people.

DR. BOWMAN: Oh, that's farmed out?

DR. LOTZ: That's all farmed out.

DR. OWEN: That's part of the problem.

DR. LOTZ: It's all --

DR. KHEIFETS: I think some do, but mostly they don't.

DR. LOTZ: Mostly they don't.

DR. KHEIFETS: I think Motorola does, but --

DR. LOTZ: Even -- even a bigger firm like Motorola that owns literally hundreds of sites. I mean, they may own the whole site where other people --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- are even putting their antennas, they tend to subcontract out that work. It's not part of their workforce. So that's what makes it really hard to get a handle on that population.

But the marketing people, sales marketing people, as far as just phone users who have really high use rates, would be a group that might have -- you know, they certainly have the higher end of the phone itself. But as far as the other kind of groups --

DR. BOWMAN: Are these CTIA members or are service providers not --

DR. OWEN: No, service providers are the majority of CTIA membership. The manufacturers are now

24 members, but only a few years ago did they really join in.

25 It's -- my understanding is that most of it is the service

providers. One thing that's -- that would --

DR. BOWMAN: It would certainly be interesting to see how CTIA would respond to a recommendation.

DR. OWEN: I think an interesting thing that might -- you might get in addition to, you know, say if you did what it sounded like, how could I paraphrase, just an exposure characterizational study looking at different job categories to just sort of be able to put a label on each one. But you might even find out that, say maybe the real estate agents, because they're driving while they're talking are not using the text very much.

And so they -- you might really get more than you expect in terms of identifying a highly exposed population, because you might be able to weed out the people who are mostly, you know, having it down in their hand and -- and by virtue of that getting lower exposures than people that are -- because of what they're doing, have to hold it up to their head.

Conversely, they might be the people that are using mostly car phones and getting the lowest. But you don't know until you do the study.

DR. KHEIFETS: Well, I mean, the other -- the other -- I don't know whether that's a legitimate

25 suggestion or not. But perhaps one could institute -- I

mean, if this was an important potential exposure, I mean, I think after some preliminary work that -- that would say that those are the people, let's say who are really getting exposed, I mean, the recommendation might be to try to keep track of those people in a kind of registry wave, so that in the future you could do a study.

I mean, the fact that, you know, the stuff that's out-sourced, I mean, that's kind of disingenuous to kind of say, well, we can't study those things because they are -- you know, if they are truly potentially an important cohort, then, you know, it shouldn't be an advantage to farm that kind of stuff out. I mean, it could have to -- somebody --

DR. BOWMAN: It could be made a condition with the subcontract that you participate in the study.

DR. KHEIFETS: Or at least as some sort of -- I mean, yeah, I mean, some sort of definition of a cohort or something that could be put in place that,

you
know --
DR. LOTZ: So --
DR. KHEIFETS: -- you collect some data
for the future even.
DR. LOTZ: I was going to say that what I
was hearing --
DR. KHEIFETS: Yeah.

DR. LOTZ: -- you know, triggering my thought was maybe begin to try and identify the cohort, even though you don't officially really begin to study them at this point.

DR. KHEIFETS: Right. No, no. That's right. That's what I mean, maybe you can't do the study, but maybe you put --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- something in place that would enable one to do it eventually somewhere down the line.

DR. OWEN: Perhaps, you know, if you got some laboratory data down the road, then you could more quickly jump to using that cohort in the study to --

DR. KHEIFETS: Yeah, if the cohort is not there, you will never be able to do anything with that.

DR. LOTZ: Right.

DR. BOWMAN: And the preliminary parts, the exposure assessment, that could be done, you know, as soon as they get the, you know, the person identified and the companies rounded up.

DR. LOTZ: And it -- and it --

DR. BOWMAN: You could do it both with marketing people and the service providers themselves and

the maintenance contracts.

DR. LOTZ: There's another new development that's just within the last about six months or so that's also rather enticing in that respect. And that is, there is, for the first time, an RF data logging personal dosimeter on the market. NARDA has put one out.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: And --

DR. KHEIFETS: Yeah, I mean --

DR. LOTZ: So that's the first of that kind that you can actually go and begin to --

DR. KHEIFETS: Yeah.

DR. LOTZ: -- go and begin to have some -- something besides spot measurements.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: And that, plus the software-modified phones for the cell phone usage --

DR. LOTZ: Yeah.

DR. KHEIFETS: Yeah.

DR. BOWMAN: -- it shows there's the technology there to really start collecting data and collecting exposure data.

DR. KHEIFETS: I mean, you would -- you would have to do the exposure assessment to even find

out

24 what kind of information to put in the cohort. I mean

--

25 DR. LOTZ: Right.

DR. KHEIFETS: -- just sort of the basic information, how many antennas were around.

DR. LOTZ: Um-hmm.

DR. KHEIFETS: Were the on or off? Or -- I mean, I don't -- some real basic stuff, you might be able to do to weed out. It could be very difficult and expensive for the future use.

DR. OWEN: What is the -- you guys probably know the most. What is the scope of use thus far for that new NARDA personal dosimeter? I mean, it's recently developed. What's it been used for thus far?

DR. LOTZ: I don't know.

DR. OWEN: You know, any -- any formal studies?

DR. LOTZ: I don't know if -- the guy who probably knows the most in our group would be Dave Conover. But, I, other than buying one, I don't know if we know too much about who else has bought one at this point.

DR. BOWMAN: I haven't even seen it

yet.

DR. LOTZ: Yeah. It wasn't in -- it's --

it's very recent. Last August it was being kind of announced, but wasn't quite out yet. So it's less than six months old. I don't -- I don't know what the --

DR. BOWMAN: And it's an exposure meter,

not a body current meter.

DR. LOTZ: Right.

DR. BOWMAN: Okay.

DR. KHEIFETS: Yeah. I mean, the same thing for this -- this NRPP, I think --

DR. LOTZ: Yeah, they've got --

DR. KHEIFETS: -- to see what each one's --

DR. LOTZ: Right.

DR. KHEIFETS: -- what the differences are between the two.

DR. LOTZ: Um-hmm.

DR. BOWMAN: And NIOSH, Dave Conover, has been working on a more fundamental issue of exposure, which is body currents. And -- and there the dosimeter is either a wrist or ankle cuff that also can monitor exposures.

DR. KHEIFETS: Who was this?

DR. BOWMAN: Dave Conover.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: He's our senior RF exposure person.

DR. LOTZ: Right.

DR. OWEN: Do we look to see him retained?

DR. BOWMAN: Oh, yes. He's retiring --

DR. OWEN: He's near retiring.

DR. BOWMAN: -- in a couple months.

DR. OWEN: Is he PHS?

DR. LOTZ: Yeah, he's PHS.

DR. OWEN: PHS retirement.

DR. LOTZ: That's the dilemma. He's not -- he -- he's not ready to quit, but he --

DR. KHEIFETS: What's a PHS?

DR. OWEN: Oh, these guys in uniform.

DR. BOWMAN: PHS is public health service promotion coordinator --

DR. KHEIFETS: I see.

DR. OWEN: That can be forced to retire. Or have -- you have a time limit?

DR. LOTZ: Yes.

DR. BOWMAN: After 30 years, you're out.

DR. LOTZ: 30 year service limit. Anyway, he's coming up on that, which is what Russ is referring to.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: That's almost a daily topic on my agenda at this point.

DR. BOWMAN: Did you -- if we've exhausted the occupational issue, did you want to go back to what

the Interphone Study was doing with the software-modified

phones?

DR. OWEN: Yes. And we -- we can always, you know, as you can tell, this is a very loosely organized meeting. This is actually an excellent time, because now we have Brian. For those of you who have not met Brian Beard before, he works in the division of physical sciences in CDR, which is the Office of Science and Technology. Welcome. Glad you could make it.

DR. BEARD: Thank you.

DR. OWEN: Howard Bassen was at the meeting a couple weeks ago, and Brian works with Howard. And so, presumably, they would bring overlapping expertise to the table. And I was hoping that we would get back into the details of exposure assessment with Brian here.

So this is actually a real good time to go back into what I -- we had a short break. And I said that, while we mentioned at several points of discussion already this morning, that there are pressing needs or critical needs for better exposure assessment, that the epi studies are built on. I'd like to hear more in detail.

And I suggested, particularly since Joe knows so much because of his involvement with the IARC, coordinated the Interphone case control studies in Europe,

and his involvement in the exposure assessment aspect of

that, that perhaps we can sort of kick back off that discussion of details with identifying what gaps there may be yet standing, even though we have this ongoing study that presumably will, in its various parts, address some of the currently existing gaps in exposure assessment.

DR. KHEIFETS: At some point, maybe not now, but later, I mean, I think we would be remiss if we didn't discuss the studies around, or populations around antennas and base stations.

DR. BOWMAN: Um-hmm.

DR. KHEIFETS: And I know that that's an unpopular topic, in that all, most of the recommendation really says exposures are so low and we shouldn't do those studies. I think we should talk about it, even -- same conclusion.

DR. OWEN: Agreed.

DR. KHEIFETS: -- if we come to the

DR. OWEN: Agreed.

DR. BOWMAN: Okay. The IARC Study uses, in a supplementary way, to its main exposure assessment, which is a questionnaire, the software-modified phones.

I don't know if it's all. But at least the major phone manufacturers have each come up with a software-modified phone. Motorola's is the most sophisticated, because it has a gyroscope or cubist eye on

it. One of the designers was at the previous meeting. And, you know, so Russ probably knows more about the Motorola phone than I do.

But the other manufacturers, what they're primarily recording is the power transmitted in the -- the frequency protocol, analog or digital, in which that transmission is taking place. And so the results over time is the level of power that the phone is transmitting at.

And I'll pass this around. But this is just 12 minutes of a number of different calls at a fixed location in an urban area very close to a base station.

DR. KHEIFETS: Why does it look like it's cut off? I mean, is that the maximum?

DR. BOWMAN: Yeah, that's the maximum

power.

DR. KHEIFETS: It's the maximum power or the maximum that -- what the -- of recording?

DR. BOWMAN: That's the highest level -- no. It goes up to zero. It can record up to zero. But depending on the phone, how much of that range they actually use, you know, is different for different phones.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: But that range works for us across all phones. And the up and down thing is what the

phone goes through in trying to seek out the most efficient hookup with the different base stations.

DR. OWEN: This -- these are the data --

DR. KHEIFETS: So this is upside down?

DR. OWEN: -- collected in --

DR. KHEIFETS: So this is the load? I don't understand.

DR. BEARD: Is this DBM?

DR. BOWMAN: Yeah.

DR. OWEN: Yeah. So that's why it's upside down.

DR. BOWMAN: Each of the levels is two DB.

DR. KHEIFETS: Uh-huh.

DR. BOWMAN: And it's set up so that the highest power is at the top. So it's --

DR. KHEIFETS: Um-hmm. Um-hmm. Um-hmm.

DR. BOWMAN: So even though the numbers go down, the power is still at the top.

DR. OWEN: And you say these data on this particular figure were collected at a single base station.

DR. BOWMAN: Right.

DR. OWEN: And so it's logging all the calls that are --

DR. BOWMAN: Right.

DR. OWEN: -- served by that base station

--

DR. BOWMAN: Yeah.

DR. OWEN: -- within a certain time period?

DR. BOWMAN: And like with most dosimeters, you have a tradeoff between collecting all that data over time or whether you're going to summarize it.

DR. KHEIFETS: And how quickly is it sampling or --

DR. BOWMAN: My -- I think it's every 15 seconds, it -- it checks its power level.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: But what it actually stores in memory is -- is more of a cumulative thing. So what we're actually going to be working with is for each period, the duration spent at these different power levels. So -- but are broken out by frequencies, so one can distinguish analog versus digital. Or in the case of -- what's the third generation stuff?

DR. OWEN: Digital 3-D, yeah.

DR. BOWMAN: Yeah. Right. Yeah. Different digital transmission protocols.

DR. KACZMAREK: A question regarding

retrospective exposures. The power levels are dependent

upon the distance to the base station. Clearly, the number of base stations have increased over time. I mean, there may be some reason to adjust for that in the context of the data, to recognize that this call that you're measuring, I mean the base station may be a relatively short distance away from the caller. But if you go back in time, there may have not have been such a base station in close proximity to the caller. The power may have to have been greater in order for the call to go through.

DR. BOWMAN: Well, that's certainly a plausible scenario. Unfortunately, we don't have any data on it. It's -- well, I wouldn't say that. Certainly, a person could work at modeling the distribution of base stations over time and -- and, you know, work out a model that would extrapolate from the density of base stations to, you know, average power levels emitted. I think that -- that could certainly be looked at.

DR. LOTZ: It's complex, though, because even like the changing of frequencies to some of the digital transmissions at higher frequencies necessitated an increase in the number of base stations, because the higher frequency doesn't penetrate as, you know, penetrate as well, cover hillsides or terrain differences. So they need more antennas.

It doesn't necessarily lower -- you know,

so that -- so you'd have to factor those kind of modifiers into it, rather than simply the distribution of base stations. So --

DR. BOWMAN: You know, having done models similar to that with ELF, which, of course, are a totally different set of variables, that's the kind of thing that, as an exposure assessment modeler, I can, you know, wave my hands about. But whether you would, in the end, come up with a model that you'd want to take to the bank is another question.

DR. KACZMAREK: Sure.

DR. LOTZ: And the other element of that involves, Balzano was saying two weeks ago, that even in an urban setting, you can't necessarily assume that the base station you're in contact with is the nearest one because of shadowing of buildings.

DR. OWEN: Yeah, that's what I was just going to diagram here.

DR. KACZMAREK: And that's --

DR. OWEN: That this is sort of your conventional cell. You know, these are base stations. That if you're out, you know, driving on the interstate or, you know, out in a more rural or suburban area, that it is pretty straightforward to know which base station

you're communicating with.

But in the urban setting, when you've got all these buildings interspersed in here, Q. was pointing out that you might be walking along the street here, and because of reflections and so on, you may actually be switching between this station and that base station and this one in providing service over time. So it is very complex.

DR. BOWMAN: And that's where the up and down pattern in that graph is a reflection of that constant probing trying to find the select base station they want to hook up with.

And it's pretty sobering to realize that that was -- had a call pattern close to a base station. So even, you know, you would think, under that situation, you'd hook up with a base station and stay there. But, clearly, that wasn't happening. It was continuing to probe.

DR. OWEN: So this is actually -- maybe I asked the question the wrong way earlier. These are actually the data off of one phone?

DR. BOWMAN: Right.

DR. OWEN: Okay. Tracking one or three calls or --

DR. BOWMAN: Right. Where you can -- where the line breaks --

DR. OWEN: Where it breaks there, so, yeah. So a small collection of calls, but all on a single phone.

DR. KHEIFETS: But it's checking with the base station, even if it's not -- you're not talking, right?

DR. BOWMAN: Now you're getting beyond what I can answer.

DR. LOTZ: Yeah. No, they are -- they're constantly -- unless you turn --

DR. KHEIFETS: So why isn't that reflected --

DR. LOTZ: Unless you turn the phone off --

DR. KHEIFETS: Right. So why isn't that showing there?

DR. LOTZ: It may be a lower level. I don't know if I can answer that.

DR. OWEN: It might be -- I think it -- this might be tracking a single channel essentially. And that might be a separate channel, the peak.

DR. LOTZ: Yeah.

DR. OWEN: I think the peak might be a separate channel. But I'm not sure about that. I don't

-- maybe, Brian, you know the most about the exposure from

the peeps, from the non-conversation?

DR. BEARD: I don't know that much about the inter-workings of the cell phone system, though. I -- I measure a lot of SAR, but --

DR. OWEN: Yeah. It's -- it was remarkable to me at the meeting a couple weeks ago, to find out how little we still know about what seems like readily available, or what seems like it should be readily available data with respect to the exposures that one typically gets in a known-use situation.

DR. KHEIFETS: So it seems that that's what we should build on, answering those basic questions about exposures, before we could, you know, move any further. It's exactly that. I mean, what are --

DR. BOWMAN: When NIOSH identifies an agent that really would seem to justify a serious look, usually the exposure assessment part goes on in parallel with assessing the epidemiologic resources. And by working parallel that way, you come to a point where you can put down plausible epi designs --

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: -- and assess the

feasibility. So it's -- if -- and I would certainly say that better quality epidemiologic studies should be investigated. But even the Interphone Study, as good as

it is, both has the limitations of a case control study and being retrospective is going to have limitations in exposure assessment.

So it would seem to me that -- that it wouldn't be, let's do the exposure assessment first and then think about the epi. That would really be assessing the epidemiologic resources potential study populations, should -- should go along with the exposure assessment, however.

DR. KACZMAREK: Some comments regarding prioritization. Russ mentioned that as a goal of the meeting. I think there's some easy principles we can probably agree on very quickly that we could make explicit.

And I think the first of these is that epidemiologic studies, study the areas of the body where the RF dose is the greatest, which is essentially the brain and the head, not to look, for example, for an increase in the incidence of cancer of the pancreas. Can we agree on that? It's a pretty straightforward

principle. But at least this will help explain, why we're studying certain things and not studying other diseases.

And the second point I was going to raise is that all diseases are undesirable, but they're really not created even -- equally. And that is, some are

materially much worse than others; for example, high-grade gliomas. Survival from high-grade gliomas can actually be measured in weeks. It's a very aggressive tumor. Conversely, acoustic neuromas are almost benign in all instances.

Both of those are, you know, are unfortunate occurrences, but the gliomas are clearly worse in terms of lethality. And it might be useful for us to establish a principle that will give greater priority to essentially more lethal conditions, conditions with a higher mortality rate.

And, again, I think that might make the FDA's or CTIA's thought process more explicit for the public, why we're looking at disease X, and we're not looking at disease Y, or we're giving it a lower priority.

Comments? Those are relatively straightforward.

DR. OWEN: I guess the first thing that comes to my mind is the benefit of -- if you were talking about a cohort study that you could go by those

guidelines, but you're not really restraining in the -- too restrained in the study design from the start, because you can, I guess, potentially pick up endpoints or outcomes as you go along --

DR. KACZMAREK: Right.

DR. OWEN: -- if you had to.

DR. KACZMAREK: The --

DR. KHEIFETS: Well, you would design -- I'm sorry.

DR. KACZMAREK: With a cohort study, you can look at multiple outcomes. But with a case control study, you don't -- you can only look at one outcome. So it really matters enormously. If you're going to study gliomas, in essence, obviously, you can't study cancer of the pancreas.

DR. KHEIFETS: But you could design a cohort study to answer -- you know, to be, let's say, powerful enough to address gliomas.

DR. OWEN: Yeah.

DR. KACZMAREK: Right.

DR. KHEIFETS: Then you could look at a lot of other things as well. But -- but you could design it for specifically -- but maybe somebody could say why the emphasis is in addition to the brain and, you know, head and neck tumors, et cetera. Why is there also emphasis on leukemia? Is it just a spillage from ELF, or is there a reason why --

DR. KACZMAREK: Well, there's concern. There's some bone marrow in the skull. And I think that potentially could be at risk. I mean, that's basically the source tissue for leukemia. And I think that's why

there's interest in looking at that.

DR. LOTZ: I would --

DR. KACZMAREK: Because basically you're getting --

DR. BOWMAN: I would think -- is lymphoma on the list as well, because there's also lymph nodes in the neck?

DR. KACZMAREK: Well, certainly, you have primary lymphoma of the brain, which you get an increased incidence in patients with acquired immunodeficiency syndrome. And that, again, actually would fall under the context, not truly of a brain tumor, but an intra-cranial tumor, which is actually, perhaps, a more correct term, even for meningiomas, which arrives in the meninges and not the brain itself.

So really, the term that you want to look at is, we'd be most interested in, certainly, in intra-cranial tumors.

DR. BOWMAN: Since we're talking --

DR. KACZMAREK: But you're right, primary lymphomas of the brain certainly exist.

DR. BOWMAN: Since we're talking about outcomes, should we widen out concern beyond just cancer? Should we think about neuro-degenerative diseases? And,

of course, the Swedes looked at, you know,

neuropsychological effects as well.

DR. OWEN: I guess that speaks to the comment that you made about the difference in seriousness of different cancers could be brought in to include that. The question is, who -- how is -- how is it decided which one's more serious, if you start trying to compare cancers to these other diseases?

DR. KACZMAREK: Well, I think that certainly in terms of cancer, you have five-year survival rates. You can look at the survival rates of a tumor. Obviously, glioma is much worse than acoustic neuroma. Acoustic neuroma's almost always benign.

Again, high-grade gliomas have a horrendous mortality rate. And that might be a useful objective indicator, quote/unquote, which cancer is worse, if you look at five-year survivals.

A comment regarding morbidity --

DR. BOWMAN: Before you go on --

DR. KACZMAREK: Okay. Sure.

DR. BOWMAN: -- certainly the rationale of the Interphone Study --

DR. KACZMAREK: Yeah.

DR. BOWMAN: -- was that collecting cancer data is, compared to the whole world of diseases, relatively the same, no matter what kind of cancer you're

talking about. So they included any cancer that could be arguably related to the cell phone radiation.

DR. KACZMAREK: Right.

DR. BOWMAN: So they didn't really have to do -- prioritize within that. But clearly they named cancer in their IARC to begin with.

DR. KACZMAREK: Right.

DR. BOWMAN: But they -- they made cancer their priority over, say Alzheimer's Disease or Parkinson's Disease, because a -- there's the, you know, value judgment. But also, following up on the neuro-degenerative diseases, they're a totally different process. There's, you know, there's tumor registries, but there's --

DR. KACZMAREK: You don't have an Alzheimer's registry.

DR. BOWMAN: Alzheimer's registries --

DR. KACZMAREK: Right.

DR. BOWMAN: -- are much less developed.

DR. LOTZ: I think, also, just to comment back on Leeka's question, why leukemia. I think there is

spillover from ELF. But there's also -- and I'm not fresh on this. So others may be able to clarify. I think there's also some things -- didn't -- I'm drawing a blank. But didn't some of the earlier just occupational or even

the amateur radio studies suggest leukemia?

DR. BOWMAN: Right.

DR. KHEIFETS: Right. But I mean, you know --

DR. LOTZ: So, I mean, it's very loose. But --

DR. KHEIFETS: Right.

DR. LOTZ: But that's -- those -- to me, those are in addition to the -- I mean, it's strengthened by the rationale that, yes, there is bone marrow in the skull. So you have a plausible connection there to exposure.

DR. KHEIFETS: How -- very little bone marrow in the skull, right?

DR. KACZMAREK: Clearly, it's the --

DR. KHEIFETS: And it's probably --

DR. KACZMAREK: -- minority, exactly.

DR. KHEIFETS: And it's probably different for children too.

DR. LOTZ: Um-hmm.

DR. KHEIFETS: I mean, the bone marrow distribution for children is very different --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- than it is for adults. So I don't know how this was --

DR. LOTZ: So I think -- I think that actually just, you know, brings in a little bit of, yeah, there -- there's some of the right tissue there. But -- but I think it's driven more by -- by the crossover from ELF and by some of those --

DR. BOWMAN: Yeah.

DR. LOTZ: -- more crude early epidemiologic studies.

DR. OWEN: There's also --

DR. KHEIFETS: But if you're doing --

DR. OWEN: While it's -- while it's painfully small in amount, there are some mechanistic data hinting, not demonstrating anything, but hinting that maybe these things -- but then again, those --

DR. KHEIFETS: For leukemia you mean?

DR. OWEN: For cancers in general. But --

DR. KHEIFETS: Oh, for cancers.

DR. OWEN: But that could just be a factor again of people doing mostly cancer-related research, looking at endpoints that are known to be part of cancer

mechanisms. And -- and again, it's very weak data. It's certainly not data that would drive you to look at something in particular.

DR. KHEIFETS: I mean, the one finding that's most relevant probably from the ELF is this walkee-

talkee, exposure and lung cancer, in the French Canadian Study. That probably was exposure to --

DR. OWEN: Oh, the extra channel on the --

DR. KHEIFETS: The extra channel, right, which is probably -- probably was sort of an RF related channel. And so that's sort of hanging out there, but that's relevant to -- to look at, though, I mean if it was -- so --

DR. BOWMAN: And that association was with lung cancer, which is even --

DR. KHEIFETS: Was much --

DR. BOWMAN: -- further away from where you'd expect the antenna to --

DR. OWEN: Although those were push-to-talk devices.

DR. KHEIFETS: But let me ask a question.

DR. OWEN: Go ahead.

DR. KHEIFETS: Does anybody know the answer to this? Let's say, I mean, if I was interested in a total exposure, not the peak exposure. But if I was

interested in total exposure and I talked on the phone for, I don't know, half an hour a day total, but I had my phone in my pocket for 16 hours, that it was one, what would be comparison of my total exposure?

DR. OWEN: I guess we don't necessarily

know, because, for instance, we -- we established that we don't know what the SAR is from the peeps that keep it up to date with the base stations.

DR. BEARD: Yeah.

DR. KHEIFETS: I think that's a relevant question. Because if we say, well --

DR. BEARD: I also assume that would vary from one phone type to another phone type.

DR. KHEIFETS: Yeah. But in terms of the location, I mean, that -- maybe that's more -- I mean, I don't know. If it was comparable in any way, and I don't know if it is or not. But, you know, if I had it in my pocket turned on for most of the time --

DR. LOTZ: It's definitely transferring to --

DR. OWEN: It's definitely comparable if you accept the premise that the important metric is specific absorption rate and then the firmer -- the further assumption that it's cumulative over time, so that specific absorption is dose. If you go by that assumption, then, certainly, you could do that, and you could ask that question, what is the source of your maximum specific absorption.

DR. KHEIFETS: I think that would be a

relevant exposure assessment kind of a question, to even

put it in the -- in perspective where the exposure -- to what part of the body, under different scenarios. I mean, obviously, if you're talking on the phone.

DR. LOTZ: Right.

DR. KHEIFETS: But again, if you're doing it with the -- with the hand-free device, you know, what is --

DR. LOTZ: Well, one of the things --

DR. KHEIFETS: -- the situation?

DR. LOTZ: One of the things the -- you know, that relates to that is the advent of greater use of headsets. Because now you're talking about it being in your pocket or on your belt.

DR. KHEIFETS: Right.

DR. LOTZ: And you're -- still you're getting exposed to that antenna radiating, but it's to a different part of the body.

DR. KHEIFETS: Yeah.

DR. LOTZ: It's no longer to the head.

DR. KHEIFETS: But it still might be very close to the body, but a different part of the body.

DR. KACZMAREK: But a different part.

DR. KHEIFETS: Right.

DR. KACZMAREK: I think that raises a

huge

point that we need to keep our finger on the pulse of what

the exposures are and how the exposures may change over time, that the current exposure pattern may not persist.

DR. LOTZ: That's right.

DR. KACZMAREK: It may change substantially, and that could change research priorities. That's a huge point.

DR. OWEN: Yeah.

DR. KACZMAREK: Just a comment too regarding leukemia. Johansen did look at it in the context of the Danish cohort study. And, again, you know with the exposed group being cellular telephone subscribers, the standardized incidence ratio was 0.97; that is, there was no association between being a cellular telephone subscriber and leukemia. A 95 percent competence interval of .78 to 1.21.

But again, Johansen, the follow-up is very limited. Digital phone users had a mean duration of 1.9 years.

DR. KHEIFETS: Yeah. I mean, I think all those studies that we have to date are sort of, you know, good, good first try, maybe a little bit reassuring, but certainly not that informative, I would say. I mean, I -- I think that, you know, there have been too much made out of them in terms of their --

DR. LOTZ: What they --

DR. KHEIFETS: -- you know, their informativeness. I mean, I'm not saying they shouldn't have been done. I'm not saying that they are not negative. I think all of those things are true, and that's very good. But I don't know that they are really telling us that much.

DR. LOTZ: Yes. There's been more described --

DR. KHEIFETS: Other than there are no --

DR. LOTZ: Well, I liked Ron's characterization to start with. They tell us there's no short-term problem.

DR. KHEIFETS: Well, I'm not even sure that they tell us that.

DR. LOTZ: Yeah.

DR. KHEIFETS: But, I mean, they tell us that there's no huge --

DR. OWEN: Because of the faults in exposure assessment.

DR. KACZMAREK: Right.

DR. KHEIFETS: Yes.

DR. LOTZ: Yes. Right.

DR. KHEIFETS: Yeah. I mean, they're telling us there's no huge --

25 DR. KACZMAREK: They don't support

evidence of --

DR. KHEIFETS: -- short-term effect.

DR. KACZMAREK: They don't support the existence of a short-term effect?

DR. KHEIFETS: Yes, that's true.

DR. LOTZ: I don't -- this is sort of a takeoff on that. But the thought had occurred to me earlier, and I didn't ask it then. What -- you know, latency is a big question. What would you consider to be an appropriate time frame -- how much latency do we need to consider in terms of, okay, whether we decide to do another study now, whether we wait five years.

Obviously, brain cancer, what information there is, suggests a pretty long latency. What's a --

DR. KHEIFETS: It's highly --

DR. LOTZ: What are -- what's a good sort of target?

DR. KHEIFETS: Well, I mean, I think it all sort of depends. I mean, as we're totally talking out in the dark here. If we assume that, you know, the latency here is similar to other diseases, most notably ionizing radiation, you know, I would say there is a 10 to 15 latent -- years latency for most of the tumors, and a 4 to 5 year latency for leukemia.

25 Whether we're talking here about that kind

of exposure, whether we're talking about that kind of an effect, and maybe here we're talking about the, you know, promotion or progression or whatever. And then we're not even talking -- looking at the right population. We really need to look at the population that's predisposed somehow or has some sort of initiation going on at the same time.

So we're really, I mean, just have to -- we're not at the point where we could test any kind of hypothesis like that. But within general, one to two years of use, you know, is not -- doesn't feel comfortable to --

DR. LOTZ: Um-hmm.

DR. KHEIFETS: -- look at the cancer outcome. It's kind of the general sense, that it's too early to tell, especially if you start looking at the overall mortality or, you know, some kind of an effect like that. Because even if there is a disease, it wouldn't be a mortality, probably, unless it was, you know, very fatal brain cancer.

DR. OWEN: The only thing that one to two might buy you is if there was a large promotional or co-promotional effect or proliferative effect or something, you know.

DR. BOWMAN: And like Leeka said, there

you'd want to study a population that has already some initiation use.

DR. OWEN: Um-hmm.

DR. LOTZ: Would that mean that you'd want to study an older population that might -- if there were other initiating events? Cause this is an age-dependent disease to some extent, right? We talked earlier about the younger ages. But I don't know what the rates -- how the rates change with older --

DR. KHEIFETS: They start -- I mean, there is -- there is a little peak, which wasn't reflected that much in those rates. That -- what I recall is that there was a childhood -- childhood brain tumor that kind of has a -- have a peak at about 9. And then from like 19 to 30, there's very, very low. And then from 30 to 40, it starts going up.

DR. LOTZ: Starts picking up and --

DR. KHEIFETS: Exponentially, basically. And it just keeps going.

DR. LOTZ: It keeps going.

DR. KHEIFETS: Right.

DR. LOTZ: So if you thought in terms of, you know, your middle-aged business persons using phones a lot or something, that -- in the sense of that rate, and

possibly what other events are known are contributing to

that --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- does that make that a -- sort of a more profitable population to study?

DR. KHEIFETS: Probably more less profitable, I would think maybe --

DR. KACZMAREK: Is there less mobile phone use among the elderly?

DR. KHEIFETS: That's true.

DR. LOTZ: Well, I wasn't thinking the elderly, per se. But maybe kind of a middle-aged group there, 40 to 50, 30 to 50.

DR. KHEIFETS: I mean, if it's a promotional or a progression effect, maybe it just -- maybe it doesn't even change the rate. But maybe --

DR. LOTZ: Beyond when you see it.

DR. KHEIFETS: Yeah. Which would maybe change the --

DR. LOTZ: Which would shift that curve --

DR. KHEIFETS: -- onset or something like

that. With the -- with the breast cancer early exposure, for example, with x-rays, I mean, with the ionizing radiation, there is some of that effect involved in earlier onset.

DR. LOTZ: Which is probably really

almost, I mean, extremely difficult. Other than a major cohort --

DR. KHEIFETS: It's very hard to -- yeah.

DR. LOTZ: -- you wouldn't be able to --

DR. KHEIFETS: It's very hard to develop, yeah.

DR. LOTZ: It'd be hard to spot that. But I guess, I don't know, just taking that thought a little farther. If you were --

DR. KHEIFETS: There is an overall increase of brain cancer, right? I'm sorry to interrupt.

DR. LOTZ: No, that's fine.

DR. KHEIFETS: Is that true, or not true?

DR. KACZMAREK: No. That's a point I'd certainly like to address for the record.

DR. KHEIFETS: Okay.

DR. KACZMAREK: A lot of people think we're experiencing an epidemic of brain cancer. And the SEERS data simply do not support that. That is between 1990 and 1998, the rate of brain and nervous system cancer, according to SEERS, has actually gone down. It was 6.5 in 1990. This is per hundred thousand, age-adjusted rates. It's 5.8 in 1998.

And, again, the SEERS system is an

excellent source of cancer -- or incidents data. The case

ascertainment levels in the SEERS system are actually in excess of 98 percent. So --

DR. KHEIFETS: Um-hmm.

DR. KACZMAREK: During the period when --

DR. KHEIFETS: Is there a different --

DR. KACZMAREK: -- mobile phone use increased rapidly, there certainly was not an increase in the brain and nervous system cancer rate.

DR. KHEIFETS: Was there increase in brain -- in childhood brain tumors and among elderly? Is there a --

DR. KACZMAREK: Well, again, we -- the overall rates, again, it's all races, you know, it's --

DR. KHEIFETS: Um-hmm.

DR. KACZMAREK: It's -- and it's actually significantly lower. The annual percent change is negative 1.3 percent.

What a lot of people think -- make the comparison to is, they go back to 1973. And then they say, like between '73 and '90, there was an increase in the brain cancer incidents rate.

And there's really a profound reason why there could have been an increase, and that was a major revolution in diagnosis. Conventional x-rays don't pick

up the major -- don't detect the majority of brain

cancers. So that is the standard skull series. You can't see inside the skull. So if the tumor doesn't have an effect on the skull, you simply can't detect it.

With the advent of CT scanning in the '70s, for the first time you got, non-invasively, a cross-sectional image of the brain. And it was extremely sensitive and specific in detecting brain cancer. And this could be done non-invasively.

In the past, they actually used to do angiograms and look for displacement of tumor vessel -- of vessels by the tumor, to make the diagnosis. And that's got considerable morbidity and mortality risks. You wouldn't simply order that test very lightly. But a CAT scan is non-invasive. So the patient who complains of a headache, one would feel comfortable in ordering a CT scan for that patient.

And even going a step beyond the CT scanner, the MRI scanner is even more sensitive and more specific in the detection of brain tumors.

So I think the increase that many people refer to between 1973 and 1990, may have largely been a function of this revolution in diagnosis.

But the key facts are, between 1990 and 1998, we have not seen an increase in the brain cancer

incidents rate. Although, unfortunately, the SEERS data,

the most recent data, only goes up to '98. We, obviously, need to look at the 1999 data and the 2000 data and data beyond. But between '90 and '98, there is no increase.

DR. KHEIFETS: For even for the age specific increases, as well?

DR. KACZMAREK: Yes, I believe so.

DR. LOTZ: Ron, how much does it change -- you were reading earlier --

DR. KACZMAREK: Right.

DR. LOTZ: -- like, you know, teenage, young adult rates.

DR. KACZMAREK: Sure.

DR. LOTZ: How high does it get in, say 50 to 60 year age range? Is it -- is it just a tiny increase? Is there quite a bit.

DR. KACZMAREK: The elderly range between about 17 and 20.

DR. LOTZ: Okay. So it does go up substantially.

DR. KACZMAREK: Right. Yeah, because the overall age specific rate is 5.8. So it's approximately three times as great among the elderly.

DR. LOTZ: That would have some variance on --

DR. KACZMAREK: And it's about half as

great in the pediatric population, approximately.

DR. LOTZ: Okay. If you were -- if you were designing a cohort study, though, that would have some bearing on your relative powers of detection, though, right --

DR. KACZMAREK: That's correct. Right.

DR. LOTZ: Which -- what kind of ages you were studying?

DR. KACZMAREK: Sure. That needs to be, certainly, factored into the study design.

DR. KHEIFETS: So do you believe -- I mean, I actually was aware of all these arguments about, you know, the diagnosis. But do you believe that it just shifted the diagnosis to an earlier time, or it really changed the diagnosis rates?

DR. KACZMAREK: Well, I think that a lot of people may have, unfortunately, expired with brain tumors, and people thought it was a hemorrhagic stroke. Again, the most common presentation for a brain tumor are very non-specific symptoms that half the planet has, things like headache. And I think you're not going to order an angiogram on a patient with a headache. But, you know, the patient provides a reasonably consistent story, you may order, depending upon your HMO, a CT or today an

MRI scan --

DR. KHEIFETS: And make a diagnosis.

DR. KACZMAREK: -- to make that diagnosis. So I think --

DR. KHEIFETS: But if we talk about --

DR. KACZMAREK: Right.

DR. KHEIFETS: -- mortality --

DR. KACZMAREK: No, no, no. I'm talking about incidents.

DR. KHEIFETS: Oh, you're talking about incidents. I see.

DR. KACZMAREK: I haven't talked about mortality at all.

DR. KHEIFETS: I see. Okay.

DR. KACZMAREK: I've exclusively talked about incidents.

DR. KHEIFETS: Okay.

DR. KACZMAREK: I have not talked about mortality. All those numbers were incidents numbers, not mortality numbers.

DR. KHEIFETS: I see.

DR. KACZMAREK: So I think there's very strong reason for us to have a much greater ability to detect brain tumors than what we had in the past.

DR. OWEN: Can you speak to the mortality

question? Any change in --

DR. KACZMAREK: I don't think our therapy has improved substantially. But, again, in terms of the issue that we're most concerned about, is there some sort of association? We care most about the incidents -- relationship between the incidents of brain tumors and the use of mobile phones, any potential relationship there as opposed to mortality.

DR. KHEIFETS: I didn't bring any data, but -- unfortunately. But I do recall that there was a slight, like few percentage increase in childhood brain tumors over the years, even beyond the '90s. But I don't remember that for sure. But that seems to me that it was the case, but I don't know.

Does it have the age specific data for the changes?

DR. KACZMAREK: What I brought with me, unfortunately, doesn't go back over time.

DR. KHEIFETS: Uh-huh.

DR. KACZMAREK: It's just the most recent data.

DR. KHEIFETS: I see. Okay. I just remember reading also a review on that. It seems to me that was the case. It was just like -- we -- that could be easily checked. I just don't remember that for sure.

Greg, you were making another point before

we went over to this. I'm sorry. Were you? I think you were making another point. Oh, it was the age-related --

DR. BOWMAN: One thought that I had from this discussion is that with adult brain cancers, the latency issue would seem to, you say, you know, the jury's still out. Well, the childhood brain tumors, obviously need less latency in making them more sensible to look at. So that -- that's again an issue of we're again looking at the resources, looking at exposures, you know, would be important tasks to probe whether that's a fruitful avenue for an epi study.

DR. OWEN: One -- in looking for more details about exposure assessment needs, I'll mention something that's kind of way off at the edge and see what you guys respond to. But let's -- my understanding is that right now the only dose or the dosimetric that we know anything about is based one way or another on SAR, on specific absorption rate.

Now, we -- as Leeka and others have discussed, we don't know whether, even given that, when looking at the kind of endpoints that we're talking about, the non-acute endpoints, we don't know whether it's cumulative and what you -- and what really you even mean

specifically, when you say cumulative, do you just simply mean integrating over time the rates that you have a

specific absorption or whatnot.

I say that as introduction to this question: what data might one want to or need to collect if there is some other more relevant dosimetric that's independent of SAR? This was discussed a little bit at the meeting that we had a couple weeks ago, but not -- not at length. It was actually brought up in open discussion rather late.

I'll give a for instance, maybe. The exposure from a wireless phone in the -- particularly, you know, when it's used at the head. So you've got sort of a combined, largely near field, but sort of a combined near field/far field exposure. All right? So it gets to be quite complex compared to the exposure from a base station or any other fixed transmitter that's any, you know, any appreciable distance from the person that is exposed.

What could one reasonably collect or might one want to collect in exposure assessment phases of study or independent exposure assessment studies that might somehow allow them to look for, maybe even later on down the road, look back and say, well, what if it's not specific absorption rate, but maybe something else?

DR. KACZMAREK: I think here's a clear need to coordinate our efforts with those of laboratory

science. I mean, basically, if there's a mechanism that

seems plausible or supported by laboratory research, I think it's incumbent upon us, as epidemiologists, to adjust our exposure assessment metrics.

DR. BOWMAN: Maybe I'm naive. But I think this is one area where the standardization of cell phone transmission signals can help, that at least the parading we're using in the Interphone exposure assessment is that if you have an analog signal that that has a carrier wave in a range of voice frequency modulations of, you know, you can pretty much summarize just by collecting a signal over a period of time.

And then standard techniques of, you know, getting frequency spectrum and averaging over time would characterize what your exposure is. And the same would be true for digital signals as well.

So basically what you're then assuming is that the dosimetry takes, again, some kind of representative signal and calculates the SAR. But even if it isn't the SAR that's important, you can still go back to the signal characteristics and look at those

characteristics.

Now, the only thing that doesn't come out in everything that I've said right offhand is that the phone circuitry itself does have -- create ELF magnetic fields directly, in addition to whatever ELF modulation

you have.

So one of my tasks for Interphone is to start measuring the ELF magnetic peels from a cell phone as it's transmitting. And I don't have -- I haven't started actually doing that, so --

DR. OWEN: So you mean those that are generated by the fluctuating current draw as the circuitry --

DR. BOWMAN: Yeah.

DR. OWEN: -- is used?

DR. BOWMAN: Right. Right.

DR. OWEN: Talk about irregularity. Boy.

DR. KHEIFETS: You know, we did this study where we measured personal exposure of not a large, but a hundred couples. And their highest ELF exposure among the phone users was certainly from -- from the phone. I mean, those who -- whoever used the phone. Their highest --

DR. BOWMAN: I didn't know you did that.

DR. KHEIFETS: Their highest --

DR. BOWMAN: I'd like to see that.

DR. KHEIFETS: -- ELF exposure -- it's been published in, I don't remember where. But --

DR. BOWMAN: Just give me the citation --

DR. KHEIFETS: Yeah.

DR. BOWMAN: -- I can dig it out.

DR. OWEN: This is a wireless phone you're talking about?

DR. KHEIFETS: Um-hmm.

DR. OWEN: And how does that compare with the ELF exposures from a corded phone?

DR. KHEIFETS: It's -- it's -- oh, corded phone.

DR. OWEN: An old-fashioned phone.

DR. BOWMAN: Virtually non-existent.

DR. KHEIFETS: None?

DR. LOTZ: No, very little. Almost nothing there.

DR. KHEIFETS: There is nothing, yeah. But basically, if you -- your exposures were somewhat different if you used the phone and they were different if you used computers. Those are the two major sources of ELF exposure, you know. Other -- so and ones who were using the phone, that was by far a substantial contribution to the -- to the ELF exposure. It was published in Epidemiology.

DR. BOWMAN: I get it. Thanks.

DR. KHEIFETS: We also, in that particular

study, it was basically a methodological study. We looked at a lot of -- we asked questions by proxy response on occupational exposures and other -- other sort of

questions about different uses. So this is something that certainly should be done.

And I mean, just in this discussion that we've moved from analog phone to digital phones, we're almost too late to capture, to really characterize exposure for analog phones.

I mean, it seems to me that one of their recommendations could be used to really try to keep up with the technology, in term of the exposure assessment. That's just as an information. So not do, you know -- I mean, whether you do a study or not. But as you introduce new technology, you kind of at least try to characterize it and how it compares with the others and, you know, keep some sort of information about that.

DR. BEARD: Doesn't that also introduce a confounded effect in all these studies? Is that if you have someone involved in a long-term cohort, and they may start with an analog phone and then switch to a digital phone and then switch to a headset, how do you do that? I mean, how do you --

DR. LOTZ: Well, an important advantage, if it's prospective, at least you'll know it. The problem with some of the existing studies and anything retrospective is, you don't have any record of what those

changes were, to speak of.

DR. BEARD: But, you know, then the exposure conditions would be changing through the course of that person's time. So how do you evaluate latency? I mean --

DR. KHEIFETS: It's very hard.

DR. LOTZ: Well --

DR. KHEIFETS: It's very hard.

DR. LOTZ: Yeah.

DR. BOWMAN: Well, one thing that this IARC Interphone study does is get a history of the person's phone numbers, both what models of phone that they're using and the frequency you use. So from the model and service provider information, you can make a stab at what, you know, whether it's analog or digital.

What is more difficult to do is extrapolate the, you know, the power distribution from present day things back into the past. And that, as we talked about earlier, is going to be a real tough thing to do at all accurately.

But at least the -- and also with the two mode phones that transmit in both analog and digital, you know, the proportion of transmission between the two is also going to change over time. So that is tough in a retrospective study.

DR. KACZMAREK: It seems clear cut that a

perspective study can obscure your exposure assessment.

DR. BOWMAN: Right.

DR. KACZMAREK: And the downside is, you have to --

DR. BOWMAN: Right.

DR. KACZMAREK: -- longer for results before a reasonable duration of use accumulates.

DR. KHEIFETS: Yeah. But, at least, I mean, if you -- if we had some information, if there were really major changes that, let's say, you know, that during '80s, you know, all phones were analogue and overall their exposure was such, if you used it for that amount of time during the day or exposure was approximately this. And then they switch to digital phones.

And, you know, on the average now people use it, you know, twice as long and the exposure's three times as much or whatever. And then -- and so on and so forth as technology changes. At least you have some general information. Right now we don't even have that.

So that would certainly be useful in all of those -- interpreting the studies that are done.

Even if it's not really definitive, it would be very useful. And also in designing studies, obviously, that would be very useful. So I think that's a

critical need, basic exposure information.

DR. BOWMAN: Right.

DR. KHEIFETS: And maybe with these personal dosimeters, I mean, some -- just using --

DR. BOWMAN: Right.

DR. KHEIFETS: -- some of the personal dosimeters for an overall kind of evaluation of exposures. Who knows? We might be surprised as to what we see once we have started measuring things.

DR. OWEN: Yeah. I think you're talking about a, you know, a big gap there and just, you know, thinking not to the future, but thinking to the present, where, you know, we're -- you know, FDA is constantly in the position of having to have a day-to-day assessment of what's going on. And any assessment has to start with characterizing exposure. And then you talk about hazard identification and --

DR. KHEIFETS: Um-hmm.

DR. OWEN: -- relative risks and so on. And so you can't do anything without knowing what the

exposure is to start with.

DR. BOWMAN: It would seem to me that to address these questions, one place to start would be a longitudinal study in a single region with the software-modified phones, so that you could look at changes in

power transmission distributions as a function of changes in where the base -- you know, the base station distribution.

It doesn't sound like an easy study to pull off. And you would probably be best off trying to find an area where there's a fairly dramatic development in new base stations so that you could see an effect.

DR. LOTZ: And that might not be as hard as it seems. Cause when you look at the coverage areas of some of even -- certainly, the major carriers in the U.S., there are still a lot of areas that aren't built out. So --

DR. KHEIFETS: So you do both. I mean, you make --

DR. LOTZ: You'd have to --

DR. KHEIFETS: -- appropriate selection.

DR. LOTZ: Yeah. You'd anticipate that those will change substantially, even yet in time to come, with existing technologies, let alone with future emerging ones.

DR. KHEIFETS: Um-hmm.

DR. OWEN: Yeah, that's -- it's because of the lack of those data that current licensing from FCC is

dependent on, you know, maximum power levels. Cause that way, at least you know, no matter what your -- what your

-- no matter what your base station is, you can figure out what a maximum level is. But it certainly could do a lot more with a true exposure assessment, compared to a --

DR. LOTZ: Potential --

DR. OWEN: -- worse case --

DR. LOTZ: Yeah.

DR. OWEN: -- sort of thing.

DR. KHEIFETS: Is FDA sort of responsible for determining the safety of the cell phones, but not base antennas? Or am I confused?

DR. KACZMAREK: That's correct.

DR. OWEN: Yeah, that's right. But FCC relies upon the FDA, NIOSH and others for the decisions that they make in terms of setting their guidelines and so on. Most notably FDA --

DR. KHEIFETS: I think NIOSH would be focusing on --

DR. OWEN: -- NIOSH and EPA.

DR. KHEIFETS: Yeah. NIOSH would focus on occupational.

DR. LOTZ: Well, the FCC, in general, has said, we look to the health agencies for guidance --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- on what we ought to control the base station transmitters to put out, or any

transmitter.

DR. KHEIFETS: Right.

DR. LOTZ: But in this case the -- and so in that respect, partly because we've been active to a certain extent, Dave included NIOSH in the -- but FDA gets far greater visibility in that picture.

DR. KHEIFETS: And is EPA involved in any way, shape, or form? Do you know?

DR. LOTZ: Well, technically --

DR. OWEN: They have some --

DR. LOTZ: -- they would be in the sense that they have historically had jurisdiction over radiation issues, in general.

DR. OWEN: Some. Some or all, yeah.

DR. LOTZ: Yeah. And depending on interpretation. But -- and in the '80s, they had a lot of non-ionizing activity.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: But in reality, in recent -- in the '90s, they had almost no -- no staff, no function --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- in the area. And so they're kind of a player, but not very active.

DR. KHEIFETS: Um-hmm.

DR. OWEN: The good -- the good thing is

that because it's a small club and we're interconnected, one -- once you have something identified, at least from, you know, usually the FDA's announced perspective of science-based decision making, so if you've identified something you need to deal with, then you can worry about who has the regulatory mechanism that's most effective in protecting the public health.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: So in reality -- unless the FDA guys disagree with me. But the FCC is the only -- only body to actually take any action in this country.

DR. OWEN: Thus far on wireless phones.

DR. LOTZ: On wireless phones.

DR. OWEN: Right.

DR. LOTZ: Because they have set limits on what they can --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: -- what they can do.

DR. OWEN: The flip side of that is that, one, they have declared that they're dependent on FDA, NIOSH, and EPA to make those decisions. And, two, they are further dependent on the consensus standards process, in which people from many agencies participate.

DR. BOWMAN: You mean in the industry?

DR. OWEN: Well, of course.

DR. BOWMAN: And the military.

DR. OWEN: And the military.

DR. KHEIFETS: Now, when we talked -- we turned to talking about children. I think I've heard somewhere, I don't know how true it is, that a lot of antennas are actually being put on schools.

DR. LOTZ: That's very true and continuing to be an issue. Where one of the reasons from the outset, and still remains true, although there have been local fights over it that have deferred it a bit. And local, I mean in individual sites or cities. That it's partly a zoning issue.

It works a couple of ways. One, the industry is willing to pay money to have a lease to put their antenna --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: -- on your site. Schools are always looking for more money. So -- but secondly, if they go to put an antenna in a residential area, they have to get a zoning change in most jurisdictions in the United States. And if they go to a commercial site, which a school would, zoning wise, would qualify, they don't. So they don't need the same variances in terms of existing ordinances.

That combination has made it a high

priority or target for the industry to put base stations on schools, hospitals, public buildings like that.

And it continues to be a fight. I mean, there -- there was a fight over a local site in Cincinnati about three years ago at a parochial school that caused the Arch Bishop Diocese of the Catholic Church in the City of Cincinnati to say, we will not have any more antennas on our school sites, because we don't want to fight that battle.

But it's -- it's a very -- it's a highly variable thing. But there have been a preponderance or certainly a likelihood of putting them on schools.

DR. OWEN: Not surprisingly, that brings you right back to the questions of exposure assessment --

DR. KHEIFETS: Um-hmm.

DR. OWEN: -- and whether, you know, putting a transmitter here increases the exposure of the people that are right here appreciably. And I think the Stewart Commission tried to be a little bit sophisticated in that, but at the same time try and put it into broader terms when they were talking about the main beam and so on. I mean, there are a lot of criticisms of the terminology use and what -- I think they were trying to do the right thing, which was be more sophisticated than they

25 otherwise might have been. But there are also problems

with doing that.

But again, the most important point, I think, is that it does bring you back again to the exposure assessment.

DR. LOTZ: And the Canadian report also addresses the fact that by numerous accounts and published studies, that the exposure on the ground around base stations is very low compared to what an individual using a phone would have, certainly with exposure to the head or the area of the body closest to the antenna.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: So it's a -- it's a wider ranging exposure in terms of more people affected. But orders of magnitude lower in the intensity of that exposure from base stations.

Even to the extent I think there's a comment in the WHO document that it's -- it sort of tried to be tactfully stated. But there would be less merit in doing an epidemiologic study on populations around base stations because the exposure is so low.

DR. KHEIFETS: Yeah, I -- I know that that's a very popular position. But my personal perspective is that that's just not going to be good enough ever, you know, unless there is really, if not epidemiologic studies, good exposure assessment studies in

those situations, to really account for all kinds of -- I mean, I am sure it's true in principle. I'm sure it's true. But --

DR. LOTZ: Well, actually there's a fair amount of data to support that it's not just in principle. I mean, in one particular school, we were looking at -- well, we were looking at exposures that you could not measure with the standard exposure instruments because they were too low. When you took in the more sophisticated instruments, you were showing levels as much as five and six orders of magnitude below the existing guideline. So --

DR. KHEIFETS: Well, I mean, that's --

DR. LOTZ: And I don't mean that --

DR. KHEIFETS: -- true, of course.

DR. LOTZ: And I don't mean to argue against --

DR. KHEIFETS: Yeah.

DR. LOTZ: -- existing guidelines, but as a relative magnitude of the exposure, it's just --

DR. KHEIFETS: See what I mean? I mean, I see all the parallels with the ELF area.

DR. LOTZ: Um-hmm.

DR. KHEIFETS: And my pint is that I see all of those arguments could be made about power lines.

Nevertheless, I think those studies were needed and they turned out to be the most informative, you know, such as they are.

But if you, you know, obviously, before you do anything, if you sit down around the table with a lot of learned people, you know, and make the arguments, that would be the argument. And it would be a true argument. Right? You would say, well, exposure from appliances. If you use a hair dryer a thousand times more than, you know, in any house near any power line and, you know, probably is true.

But again, that does not and it historically has not turned out to be a good argument. So, you know, this is -- we're talking about a very complex exposure. And the same thing you could say. I mean, an exposure in homes is certainly older, so it's not going to have be below any guidelines. That would be true too.

DR. LOTZ: Well, yeah.

DR. KHEIFETS: So all of those -- right? I mean --

DR. OWEN: I think the important thing for in -- forming the design of an epidemiology study is that if you did exposure characterization from the technology

25 that was focused on the handsets, you would certainly want

a careful exposure assessment from the other half of the technology, the base stations and to be able to put those two exposures in context with each other, so that you would know which one was giving you the --

DR. KHEIFETS: Sure. Sure.

DR. OWEN: -- relevant exposure based on what you think the relevant metric is.

DR. KHEIFETS: Sure. I --

DR. LOTZ: Well, I think, you know, what you've kind of nailed me on, Leeka, is I've often felt like I -- that the wireless industry needs to learn from the lessons of the power industry --

DR. KHEIFETS: Right.

DR. LOTZ: -- in terms of researching this topic. But at the same point, you just kind of nailed me on a particular rationale that I hadn't made the connection myself. So, yeah.

DR. KACZMAREK: I think that's --

DR. BOWMAN: Maybe this is a good time to bring up what Leeka had mentioned earlier is the body of evidence epi studies around -- around broadcast towers.

DR. KHEIFETS: Well, I mean, my personal opinion that those studies are so poor and so uninformative, that they certainly don't -- don't show

there is any risk. I mean, I don't think that there is

any hints of risk there.

But at the same time, I think that once you propagate an involuntary technology that will be, you know, close to somebody's home, you have to do at least a good faith surveillance effort to say that, in fact, you know, we've looked and the exposures are what we thought they were going to be, and the risks are not going to be there, you know, even with constant cumulative low-level exposure. And that's my point.

And then just to say that -- you know, to make other heuristic sort of arguments that were, of course, you know, non-existent, et cetera, even if it's true, it's just not good enough in my opinion. And so, that was kind of my point.

DR. LOTZ: I think --

DR. BOWMAN: That was a recommendation for you.

DR. LOTZ: Yeah, that -- no. I think that's a fair point, because, yeah, a lot of the parallels of the energy levels are too low --

DR. BOWMAN: Oh, right.

DR. LOTZ: -- and all that just --

DR. KHEIFETS: They certainly are too low.

I mean --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- but the point is, you know, without this finding --

DR. LOTZ: No. I was going to say, and then -- and in, you know, in the ELF case, we've always had the argument that even the photon energy was too low. But now you've got orders of magnitude and much greater energy in the photon --

DR. KHEIFETS: Right.

DR. LOTZ: -- with this frequency. So, you know, I think that --

DR. OWEN: But now it -- did I hear you correct -- did I understand you correctly to say that if you look at the available literature from broadcast sources of RF exposure, it doesn't tell you anything, because it's so poor?

DR. KHEIFETS: That would be my point. I mean, they have so many problems that, you know, they are sort of in cluster investigations. They're all done poorly. They're all this Texas sharp-shooter phenomenon that, you know, you draw the boundaries around something that's been already identified. They mix different diseases. You know, there's no exposure assessment.

I mean, I wouldn't say -- certainly, I don't feel where they're pointing to a problem. I am not

arguing that something should be done because there is

something in those studies. That's not what I'm trying to argue. I mean, I think that certainly those studies are extremely poor. And, you know --

DR. LOTZ: But your point would be that since those sources exist --

DR. KHEIFETS: Right.

DR. LOTZ: -- in proximity to where people live --

DR. KHEIFETS: Right.

DR. LOTZ: -- that we need to study them to address.

DR. KHEIFETS: And because people are concerned.

DR. LOTZ: Yes.

DR. KHEIFETS: And because people treat involuntary exposures and the voluntary exposures from cell phone differently.

DR. LOTZ: Right.

DR. KHEIFETS: Because, you know, there is a less of a direct benefit to them --

DR. LOTZ: Um-hmm.

DR. KHEIFETS: -- from that thing being there, just, you know, like it is with a power line.

DR. LOTZ: Um-hmm.

DR. KHEIFETS: That there is a benefit to

a person --

DR. LOTZ: Right.

DR. KHEIFETS: -- but he doesn't perceive it that way, you know, he doesn't want the big power line there because he's going to use it a little bit.

Same thing, you know, it's one thing if I'm using my cell phone. It's under my control how much I use it, whether my child uses it, you know, whatever --

what I do with it versus that being in the house. It's just a very different situation.

So it just seems to me that in the general kind of surveillance mode, good faith effort just needs to be made to do at least a couple of good studies and not just kind of dismiss it out of hand because the exposures might be so low.

DR. KACZMAREK: Yeah. I think the key is the involuntary nature of the exposure. Certainly,

there's a lot of evidence that the public is far more concerned about involuntary exposures than voluntary exposures. So there needs to be some recognition. There could be a strong public demand to look at those.

DR. OWEN: It sounds like we're talking primarily about political factors rather --

DR. BOWMAN: Well, you can also phrase

it

ethically.

DR. OWEN: It sounds like also something that -- avuncular advice from a more experienced industry in the field could give the industry jargon.

DR. BOWMAN: Well, that's where the ethical component comes in. The responsible industry should recognize they are exposing people. And it, in a broad sense, as good citizens, it's their responsibility, as well as in a legal sense, to determine the consequences of this exposure.

DR. OWEN: I find that I'm going to have to continue to pound you on this exposure assessment question.

DR. KHEIFETS: That's good. We like it.

DR. OWEN: Because I'm getting --

DR. LOTZ: Can't keep us on topic.

DR. OWEN: -- great -- no, no. It's just that I feel like I've, you know, heard a very strong, you know, input that says, we need more information. So what information do we need? I mean, I've heard, we need everything. But that's not enough detail.

DR. KHEIFETS: What we need, we need to know what is sort of the general exposure levels out there among various population subgroups. We need to know, what are the major sources of exposure in terms of the maximum

exposure and in terms of the cumulative exposure.

We need to know, how changes in technology affect those exposures. I mean, try to differentiate between the area where there is a good coverage or -- I don't know what the right terminology is. There are a lot of, you know -- versus cities where there's not good coverage, where there are only a few antennas.

So we need to, I would say, you know, use a -- both use the newly developed personal dosimeters for the overall evaluation of exposures and the use of the new -- whatever Joe calls it, computer --

DR. OWEN: Oh, software-modified.

DR. BOWMAN: Right.

DR. KHEIFETS: -- cell phones. I think we need to know what the exposures to different parts of the body, roughly, are, based on different type of the use, whether when the phone is used with hands-free device, when the phone is used just it's on but not being actually -- carrying the phone. What are the differences? And what are the total contributions of those exposure -- of those different modes to total exposures.

DR. BOWMAN: What's the status of the data on hand-free devices? Particularly after that report

in

Britain that they actually increased exposures.

DR. LOTZ: I think there's a pretty strong

-- my interpretation would be a pretty strong consensus

from other investigators, both government and industry, that there are -- their experimental setup was flawed. And that that's really a bogus finding, that there is, indeed, you know, a major reduction in SAR to --

DR. KHEIFETS: To the head.

DR. LOTZ: -- to the head, by using a hand -- an ear piece.

DR. KHEIFETS: What was this report on? I'm having a --

DR. LOTZ: The report was --

DR. OWEN: This is the Popular Press --

DR. LOTZ: Well, actually, the report was by the Consumer Association of the U.K., which is kind of the counterpart to Consumer Union, Consumer Reports here.

And they did a study, reported that the energy level in the ear or in the head could be three times higher with the ear piece, that the wire was, essentially, under certain conditions of length and orientation, acting like a secondary antenna to channel the energy from the phone to the brain.

And then they were criticized for it and set out to reproduce the thing, and published an affirming report that supported their position.

But, in the meantime, I don't know if any of these, Russ, have made it into actual published, except

for --

DR. OWEN: Ben's -- Ben's presentation in June.

DR. LOTZ: -- Ben's presentation and web site stuff may be in the industry web sites.

But -- and then there was a different organization in the United Kingdom that actually set out also to -- and they've -- again, it's all been kind of Trade Press or Popular Press stuff.

DR. OWEN: Yeah.

DR. LOTZ: But the -- anyway, the -- and there were some -- but there were some when they -- when pressed to publish their methodology -- and Brian may know a lot more about this than I do. But I think the --

there
was some apparent flaws in what they had done in terms of
their model --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- in terms of their phantom,
those kinds of things that didn't necessarily entirely
tell you exactly what went wrong, but certainly were
suspect.

DR. OWEN: Yeah. I was just sketching
that one example that somebody showed me, where if this is
a phantom that's basically a whole body phantom with a
head, and then this is the ear piece device and then this

is the phone itself. And then over hear you've got the same thing, except your phantom is just a basketball or something.

One of the problems that I heard characterized was that this basketball model was what was used to come up with this idea that there was an increase in the SAR to the head between these two scenarios. But again, that's only one piece of what the --

DR. KHEIFETS: Because of the shielding of the body? Or what's the -- what's the thought there?

DR. OWEN: Brian?

DR. BEARD: Well, I've heard the results from this too, but I have no idea exactly how they did it. But in that second case, where you have just a head phantom and the phone --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. BEARD: -- sort of off in free space, you're not loading the antenna with the body, as you would if you had it on your belt or anything. So you have a much more likelihood of pickup into the wire that's running up into the ear. One would think if it was well shielded though, there would be little of that.

DR. OWEN: This stuff hasn't been

comprehensively presented yet either in the literature.

DR. LOTZ: Yeah. Initially, the Consumers

Association was very reluctant to even reveal how they did it at all.

DR. OWEN: Which was odd.

DR. BOWMAN: Right.

DR. LOTZ: Yeah. It gave --

DR. BOWMAN: Public service.

DR. LOTZ: They reported their findings, but didn't want to give the details of how they did it.

And -- but I also -- it seems to me that there were also questions about whether the -- whether they were actually measuring energy absorption or just measuring electric field and whether they even had the head phantom filled with this simulated material or not, tissue.

DR. KHEIFETS: Right.

DR. OWEN: Yeah, there was a question about that, I recall.

DR. BEARD: I hadn't heard that. That could make a big difference too.

DR. LOTZ: Anyway, it's been a while since I looked at that. But there were lots of questions like that about what their phantom was like and how it was -- whether it was put together --

DR. BEARD: And subtle differences -- I'm on the IEEE Committee, putting together the FCC 34, you

know, the method that the FCC and everyone will be using

for validating the SAR on handsets. And very tiny differences in the phantom in the setup and positioning of the phone will make substantial differences in the SAR that's measured. And right now it's one of the things that that committee is haggling over to no end, back and forth. It is exactly how you set up the phantom and dimensions of the phantom and the positioning of the phone, because it -- it's very critical to the industry to meet that 1.6 watts per kilogram log on.

DR. KHEIFETS: Has there been any SAR measurements when not in -- like in animals or something like that, to sort of -- in vitro to kind of try to see how it compares with the phantoms and --

DR. OWEN: Yes.

DR. BOWMAN: Yeah.

DR. KHEIFETS: In what animals?

DR. OWEN: Well, in rodents.

DR. KHEIFETS: Only in rodents.

DR. OWEN: No, not only in rodents.

DR. KHEIFETS: Apes?

DR. OWEN: But there's been a huge amount done in rodents because of the desire to set up exposure systems for rodent experiments. There's been --

DR. LOTZ: But even more historically,

from other sources, not necessarily a mobile phone --

DR. KHEIFETS: Right.

DR. LOTZ: -- there's been a lot of experimental validation of the SAR models in -- primarily in rodents, but in monkeys as well, and both in the skull and in other tissues, and then using techniques like thermographic imaging of -- of models or phantoms that were, you know, then being able to open up and look at the distribution of energy inside, compare that to the computer model.

So there's really, you know, oh, I don't know, 15 years or so of kind of valid --

DR. KHEIFETS: Um-hmm. And so the models are pretty good? These kind of phantom --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- models are pretty good?

DR. LOTZ: Well, and what's primarily --

DR. KHEIFETS: I think it's driven a lot of the --

DR. LOTZ: It's driven the technology. It's sort of like you were describing earlier, that, you

know, if you have a need to answer this, then you're going to push to find out.

DR. KHEIFETS: Right.

DR. LOTZ: So for, you know, even the implantable electric field probes that are used in the

phantom came through some of that kind of development. Actually were developed by Howard's group, so --

DR. BEARD: Yeah.

DR. OWEN: Of course --

DR. BOWMAN: How do the computer models compare with --

DR. OWEN: That's where I was going.

DR. BOWMAN: -- the phantom results?

DR. BEARD: They're close. Actually, the committee that I'm on is split into two groups. There's an experimental group which I'm on, and a computational group, I have no involvement with.

But everyone seems to agree that the best way, if you're looking at a particular geometry, like a human versus an animal, is the best way to do as an experiment -- experimentally.

DR. BOWMAN: Right. So that's the goal standard?

DR. BEARD: Yeah.

DR. BOWMAN: But when you're dealing with multiple situations like multiple phone orientations and

other scenarios, do you still do it experimentally or is that a case where you would use a computer and calibrate it against the experiment for a few limited situations?

DR. BEARD: Well, that was a big point of

contention in developing the standard. Right now the draft has two positions that will be used for the evaluation.

DR. BOWMAN: Right.

DR. BEARD: And that was basically a compromise between industry and regulatory agencies that wanted more and industry that wanted less test positions, because it's expensive to do all the tests.

DR. BOWMAN: Right. And that's why I was wondering to what degree can the computer dosimetry explore the different positions, saving the need to have multiple tests with the phantoms.

DR. BEARD: I would never go solely with the computer modeling. But I would certainly use the computer modeling to sort of fill out the data --

DR. BOWMAN: Right. That's what --

DR. BEARD: -- from the experimental.

Yeah, sort of match up the points and go from there.

DR. LOTZ: Brian, does the guideline coming out allow a computer modeled submission alone, or does it require that the testing be done experimentally?

DR. BEARD: No. This is a consensus standard that says how you will do the measurements. Now, as to who will accept or not accept --

DR. LOTZ: Okay.

DR. BEARD: -- computer models, that's up to the FCC and any other regulatory agency that will say, comply with this consensus standard.

DR. LOTZ: Does the FCC accept computer modeling data at this point?

DR. BEARD: I do not know at this point.

DR. LOTZ: You know --

DR. OWEN: I'm pretty --

DR. BEARD: I think it --

DR. OWEN: -- sure that it does allow sponsors to submit their data pretty much any way they want to, you know, between --

DR. BOWMAN: In absence of a tested standard.

DR. OWEN: Yes, in the absence of the standard. But the standard is going to address both the experimental measurements and the computational measurements. And so it --

DR. BEARD: Yes, but I can't speak to what it will say in the computational area.

DR. OWEN: Right. Right.

DR. KHEIFETS: What is the difference between the two models that Maria Stuckley has and Ohm Ghandi's has?

DR. OWEN: Maybe Neal Couster --

DR. KHEIFETS: I don't know.

DR. LOTZ: Well, Couster's been primarily on the experimental side.

DR. BEARD: Yeah.

DR. OWEN: Oh, that's true. That's true. I was thinking of experimental.

DR. LOTZ: Whereas Ohm --

DR. BEARD: Ohm has been doing most of the --

DR. LOTZ: -- computational.

DR. BEARD: -- computational stuff.

DR. OWEN: Yeah. Well, I think we're in a really good part. But I made some notes to where I think we can pick back up. I think this is a good place from a blood sugar perspective and so on to break for lunch and actually, you know, be able to attack again some of the same territory with renewed vigor. Let's shoot for a 1:30 reconvene. That should give people plenty of time, I think, to -- there's a couple feeding stations within the building and whatever other needs you might want to attend

to. Abiy, you know more about what's available in the building or close to the building. Is that --

MR. DESTA: I know what's available in the building. I have no idea what's available close to the building. There's a restaurant up on the main lobby floor

that's open for brunch.

DR. OWEN: Okay. So that should be plenty of time then for people to get a meal, if they need to, I guess. I think if we spend a lot of time out of the building, then it's going to be hard for people to get back.

DR. LOTZ: Well, it's not like being downtown where there's --

DR. OWEN: Where we were before, yeah.

DR. LOTZ: -- you know, lots of stuff around the block or whatever, that I'm aware of.

(BREAK - 12:02 to 2:01)

DR. OWEN: There's a sign-up sheet outside the -- on the table outside the door of this room. And I'd appreciate it if anybody that's here around the periphery, if you'd sign up, let's us know who you are and where you're from. I've had the pleasure of meeting several of you already. But it's not mandatory, but we like to know. It's good, at least, to be able to identify witnesses.

DR. KHEIFETS: Just in case there's an erratum to be sent, right?

DR. OWEN: Yeah, that's right. Let's see if there are other -- so to try to pick up where we left

off, to a degree. A question I came up with that I

thought I'd put Brian on the hot spot with, by virtue of his membership in the FCC 34 effort, was you could probably talk a little bit about what research needs or possible research needs have come to mind as a result of data gaps that have been identified in the process of hammering together this measurement standard.

Obviously, you've got to create the standard with whatever data you have at hand. But it seems to me like a strong possibility that you would identify areas in the process that more data could be very important, very useful. If not, I'll be pleasantly surprised.

DR. BEARD: Okay. I have to admit, I haven't been involved with the committees from the beginning. Howard brought me in sort of midway along.

But since it's strictly an experimental standard, none of the meetings I've been at they talked about epidemiology or any of that. It's been very focused on the engineering details of, how do you measure, you know, the SAR, what position you hold it, and what interpolation methods you use from the E-field probed, you know, and things like that.

DR. OWEN: Yeah. I'm sorry, I didn't mean to imply that you would have overall epidemiology research suggestions. I was, I guess jumping back in too quick. I

was thinking more in terms of the exposure assessment issues that we were talking about and what kinds of specific pieces of information maybe we need more on in order to more properly do exposure assessment for future work.

DR. BEARD: Okay.

DR. OWEN: Just -- and I'm not saying this is one. But, you know, for instance, if there was a question about the composition of the tissue or equivalent gel that's used in the phantoms. Or is there research that needs to be done to determine what that is.

DR. BEARD: There's a great deal of research done in that area already. And they basically agreed to use one that simulates the brain more than the muscle tissue and skull.

And as far as parameters you were talking about earlier, that needed to be recorded for possible future use, certainly, you'd want to have the

frequency,
19 whatever, it was transmitting and the peak power that, you
20 know, just in case something comes in that's a function of
21 power levels. You know, something develops that there's
22 like a knee in the curve.
23 DR. BOWMAN: Is that -- I mean, I
24 basically assumed that if the modeling was done at a given
25 emission power, that the SAR would scale literally with

changes in the --

DR. BEARD: Right. But I was thinking more of, you know, if some biological effect or disease link is shown later, it might be, you know, where there's some threshold as far as power.

DR. BOWMAN: Right.

DR. BEARD: You know, it has nothing to do with actually measuring exposure.

DR. BOWMAN: Right.

DR. BEARD: It's just something that --

DR. BOWMAN: Yeah.

DR. BEARD: -- you had mentioned that might be a good thing to record --

DR. BOWMAN: Right.

DR. BEARD: -- for future possible use.

DR. BOWMAN: And where the testing is done, is it done at the maximum power emitted by the phone model or was it done at a standard power?

DR. BEARD: It's done at the standard power radiated by the phone.

DR. BOWMAN: Which is a set wattage --

DR. BEARD: There will be --

DR. BOWMAN: -- or is it --

DR. BEARD: There will be tests done --

let me see if I can summarize it here. There'll be an

anthropomorphic phantom.

DR. BOWMAN: Right.

DR. BEARD: Left and right sides. Two positions --

DR. BOWMAN: Right.

DR. BEARD: -- on each side. And in each position, they will have to test through the full operating collimate of modes for the phone.

DR. BOWMAN: Okay.

DR. BEARD: Whatever that may be fore that particular phone.

DR. BOWMAN: Okay.

DR. BEARD: So it develops into quite a few tests, even for just those two positions, because you have left, right. Two positions each left and right.

DR. BOWMAN: Um-hmm.

DR. BEARD: And then all the different operating modes.

DR. BOWMAN: Now, operating modes is different than power levels.

DR. BEARD: The operating mode will determine the power level, whether it's in --

DR. BOWMAN: Right.

DR. BEARD: -- conversational mode or -- yes.

DR. BOWMAN: Okay. I see what you mean. And now, within a given operating mode, the phone in normal usage, its power level is determined as to what it needs to maintain communication with the base station. So what do you set that at when you're doing the testing?

DR. BEARD: Okay. When it's in regular voice operating mode, it will go to its maximum output for that mode.

DR. BOWMAN: Okay.

DR. BEARD: It will go to the -- yeah. Okay. It will go for the maximum power for each mode that you run it through.

DR. BOWMAN: Does that vary from model-to-model?

DR. BEARD: Apparently so.

DR. KHEIFETS: I'm going to ask an extremely stupid question. Is there -- is there such -- is anybody recording what the base station outputs, just what they put out? I mean, is there a way to just record it? Does it make sense to record that? I mean, is it stored somewhere? Is it --

DR. LOTZ: I'm assuming that they have that capability. But whether they're actually doing

anything, you know, with monitoring -- and the reason I say that is because of the data that I know existed some

years ago about what the average power required for a call was. That had to do with the cell phone coming in. But it still -- there had to be records on both sides in terms of tracking what was going on.

But the -- my understanding of the base stations is, they pretty much operate with channels. Well, they operate with channels. And that it's pretty much a function -- the variation is a function of how many channels are on, not whether one channel's operating at watts or 10 watts, or that kind of thing.

DR. OWEN: Yeah. My understanding is they don't have active control of the base station power, only of the handset --

DR. LOTZ: Yeah.

DR. OWEN: -- which is driven, of course, by the need to eliminate any --

DR. LOTZ: Well, except that the base station will add and drop out channels as the --

DR. OWEN: Channels, right.

DR. LOTZ: -- load demands. So they may have as many as, I think up to maybe as many as 50 channels on a given tower. And they might be operating at one time or then go up to, you know, most of them have a peak load.

DR. BOWMAN: So Leeka's question basically

boils down to, do they keep records on the profile of number of channels operating at the time.

DR. LOTZ: And that I don't know.

DR. OWEN: I've seen some sketches of that. But I think that they were based only on the, you know, assessment of a single site, not a continuous logging of all the various --

DR. KHEIFETS: Um-hmm.

DR. OWEN: -- stations over, you know, some long period of time. I think it was basically somebody went in and studied it for X period of time, rather than --

DR. LOTZ: I can't imagine that they couldn't do that. The question is whether they store the data in a form currently that makes it convenient to do that. I mean --

DR. KHEIFETS: Is that --

DR. LOTZ: You could go back from all the billing records --

DR. KHEIFETS: Right.

DR. LOTZ: -- and reconstruct it. And I'm sure there's some log somewhere in a computer that says, it was switched from this base station to this base station, and you add up the time to make the billing record. But whether you can --

DR. OWEN: Whether those data are retained for any length of time --

DR. LOTZ: Yeah. Or whether you could sort it by station as opposed to by phone number.

DR. BOWMAN: And that would certainly be relevant to the base stations that you were talking about this morning.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: Um-hmm, yeah.

DR. BOWMAN: But whether or not that data is stored depends on the operating needs of the utility.

DR. LOTZ: Yeah, I just -- I know that even having just looked at one particular site in a passive, you know, just watching it with a spectrum analyzer, that's a very active process. It was channels dropping in and out.

DR. BOWMAN: And the channels are at different frequencies?

DR. LOTZ: Yeah, they're all separated by about a half a megahertz or something like that. Or they're -- their midpoints are separated by something like that.

DR. OWEN: Yeah, it depends on the --

DR. LOTZ: Yeah.

DR. OWEN: -- the scheme.

DR. LOTZ: Right.

DR. OWEN: Yeah.

DR. LOTZ: And --

DR. BOWMAN: Does the height of the channel stay constant? Or are you saying that just --

DR. LOTZ: I'm thinking it's pretty much on or off --

DR. OWEN: That's what I --

DR. LOTZ: -- the -- a given channel.

DR. OWEN: That's certainly what I've seen diagramed.

DR. LOTZ: And then so the total radiated power from that base station, which would have a bearing for exposure assessment will be the number of channels it's on. So that, for example, if, you know, from a practical standpoint, you want to go out and measure exposures around a base station, there's no way you're going to really hook up with that company and get them to turn them all on at once or something.

DR. BOWMAN: Right.

DR. LOTZ: So the best thing to do is go at a peak period of time, like rush hour going home, if you're in the city. So that you know that the demand is going to be the greatest, therefore, the most channels likely will be on, in terms of making your measurements.

DR. BOWMAN: I interrupted Brian.

DR. OWEN: Yeah. You were talking about the different modes. I was wondering whether one of the modes you were referring to was this sort of -- I was calling it a peak mode or, you know, the locator mode. The one that's going on all the time whenever you're -- whenever the phone is powered and not being used. So that -- so, you know, that calls can find your handheld.

DR. BEARD: Right, just the --

DR. OWEN: The hear-I-am peep.

DR. BEARD: Yeah.

DR. OWEN: Is that one of the modes that's tested?

DR. BEARD: Yes.

DR. OWEN: Yeah. Okay.

DR. BEARD: And the ring mode would be another and --

DR. OWEN: Ring.

DR. BOWMAN: Could you educate me on one thing about the software-modified phones? They record DTX status. What would that be?

DR. BEARD: I don't know about -- there is software modification that they will make to do the certification testing under the standard, which will be to

allow it to maintain full power in all the modes.

DR. BOWMAN: Right.

DR. BEARD: But are you talking about that software modification? Or the one you were talking about earlier that --

DR. BOWMAN: Well, this is --

DR. BEARD: -- sort of logs the power over time?

DR. BOWMAN: This is just the write-up of the results from the software-modified phones. And they record operating parameters that are -- even though the phone itself is modified, the modification is just to record the normal operating parameters. And one is whether this DTX status is active or inactive. So I was just wondering -- I just can't recall what DTX was.

DR. OWEN: Do you know what DTX is?

DR. LOTZ: No, I don't know. But I did wonder about those modified phones, whether in addition to power they record whether it's just on or off. I mean --

DR. BOWMAN: Whether the phone itself is on or off?

DR. LOTZ: Yeah.

DR. BEARD: They must because they record time of use.

DR. BOWMAN: I think they're recording

power transmitted. So if it were either in a passive mode

or totally off, I guess it would be --

DR. BEARD: It would be zero all the time.

DR. BOWMAN: Right.

DR. BEARD: So you wouldn't know if it was in your shirt pocket, like you were saying earlier --

DR. KHEIFETS: Um-hmm, um-hmm.

DR. BEARD: -- on, and peeping every now and then.

DR. OWEN: So the question is, do we know whether the dos phones are tracking the peep. I would -- I don't know the answer to that, even though I've seen a lot about that phone. My guess is that it would be possible, but might not be included because it would be known not to vary, other than whether the phone was switched on or off.

DR. LOTZ: Yeah.

DR. OWEN: The peep rate is presumably fixed.

DR. BOWMAN: Right. So that you could calculate that emission from the time that it was off.

DR. OWEN: Yeah. Although, certainly, all these other functions had required time, date stamp.

DR. BOWMAN: Um-hmm.

DR. OWEN: So there probably is a power on

and off function, but I don't know. I don't know for

sure. That --

DR. BOWMAN: That's a good question.

DR. OWEN: Yeah. In that phone, there's -- I guess you were mentioning it. There's actually three or four different flavors of that phone --

DR. BOWMAN: Right.

DR. OWEN: -- which are all software modified.

DR. BOWMAN: Right.

DR. OWEN: But then there's the one, which is the dos phone, the Motorola device --

DR. BOWMAN: Yeah.

DR. OWEN: -- which has a lot more on board than just the software modification.

DR. BOWMAN: Yeah. I've got the list here. The other companies making these phones are Eriksen, Alkatel, and Nokia. And, of course, Motorola has the super phone.

DR. BEARD: Well, I hadn't heard about the dos measurement phones before. So --

DR. OWEN: We'll have to send him that link if it's still active. There was a link that the group at MIT -- a group at MIT did work developing that phone for a while, anyway. I don't know if it's still

active. They had a link where you could actually get

video of it operating.

One of the things it had was, I guess, at least two, two or more couplings to be able to sort of triangulate the position of the phone with respect to the head and super -- you know, collect that data as well, so that you could figure out, based on the geometry of the phone and everything else, how far the radiating structures actually were from tissue, to allow fairly sophisticated SAR calculation being created.

DR. LOTZ: Q. Balzano was pretty emphatic that it could do that when -- in, you know, his comments about it. So I'm sure that it's --

DR. BEARD: Q's not with Motorola anymore though. He just retired.

DR. LOTZ: Right. So he --

DR. OWEN: But we had him two weeks ago at our meeting here in Cincinnati.

DR. LOTZ: Yeah. What happens in the future -- maybe he'll be doing it independently. But anyway, in talking about what it could do, in fact, he even said that it had an accelerometer that could tell whether it was the right side, left side.

DR. OWEN: Yeah, he did say that.

DR. LOTZ: So that you could actually

tell

laterality with the data logging, which is a pretty nifty

feature of it that -- in terms of information you like to know in the exposure assessment.

DR. KHEIFETS: That's the other thing that, in general, if one does an exposure assessment in general, that certainly could be done as well, is to find out whether people tend to use it on one side or tend to switch back and forth. And that kind of information could be easily ascertained too.

DR. LOTZ: Yeah.

DR. BOWMAN: This is one area where the Interphone Study with the Motorola, as well as the other software-modified phones, will greatly, you know, increase our basic understanding of these kind of exposure questions.

DR. KHEIFETS: But there is no U.S. component to that study.

DR. BOWMAN: Well, that's an interesting issue from the FDA point of view. I don't know the full story as to why the two U.S. centers that had --

DR. OWEN: -- submitted --

DR. BOWMAN: Yeah. -- did not get included, or get funded or whatever.

DR. OWEN: Well, let's say the Interphone probably didn't provide the funds.

DR. BOWMAN: No, I no.

DR. OWEN: And so they didn't get funded.

DR. BOWMAN: Everybody -- everybody had to get funding for their own local entity epidemiologic effort.

DR. OWEN: Yeah.

DR. BOWMAN: The Interphone Study is providing the protocol and -- of the software-modified phones and infrastructure. But each site had to get funding. And --

DR. KHEIFETS: Who -- I know Susan submitted one.

DR. BOWMAN: Right.

DR. KHEIFETS: And who is the other one?

DR. BOWMAN: There was also an investigator from Chicago, I think.

DR. OWEN: Faith. Faith. What's her last name?

DR. LOTZ: I've forgotten too.

DR. OWEN: But she was partnered a little

bit with Jim Linn.

DR. LOTZ: Um-hmm.

DR. OWEN: Jim Linn was involved in --

DR. LOTZ: Absolutely.

DR. OWEN: -- in that proposal. Her name slips my mind.

DR. BOWMAN: So they submitted like grant proposals and they were funded through --

DR. OWEN: Well, I don't know who they --

DR. LOTZ: I don't know either.

DR. OWEN: -- might have submitted proposals to. I doubt they ever did, because I don't think there was anybody requesting proposals to fund. I mean, I'm -- and they -- they certainly were poking around and probing for funding sources. I don't know for a fact whether either of those groups actually submitted proposals to anybody that had money. We didn't have money.

DR. BOWMAN: Maybe time ran out or maybe --

DR. OWEN: Oh, on the Interphone.

DR. BOWMAN: Yeah.
DR. OWEN: Yeah. Yeah, they -- yeah, I think they missed the -- although, certainly, my understanding is the Interphone project was anxious, would have liked to have had --
DR. BOWMAN: Oh, yeah.
DR. OWEN: -- at least one of them involved and, you know --
DR. BOWMAN: There's always been sort of a -- well, not always. But at least some people sort of

claim, well, if they -- if the Interphone Study finds something, that doesn't necessarily apply to the U.S. And, you know, while the global technology is relatively uniform, the political perceptions really have to be dealt with. And to a certain degree, I guess that's in your court to sort of frame it as, you know, the Interphone Study's going to provide important information and this is, you know, research needs to pursue this --

DR. OWEN: Certainly the political perceptions are outside the scope of this meeting. But that does -- I did ask earlier if we had any reason to think, or do we have information that we could use to know whether there would be a difference in the exposures to U.S. users versus non-U.S. users. And so I'm not sure I got --

DR. KHEIFETS: What's the different distance between the skull and the brain?

DR. OWEN: Interestingly I think it was at the meeting two weeks ago that someone explicitly made the point that they did not think that there was a biological heterogeneity between the users in the U.S. and other

users. That was one person's opinion. Maybe you've got --

DR. KHEIFETS: It was better put.

DR. OWEN: Maybe you've got a different

opinion. But certainly, it just seemed reasonable to me that a number of other factors that could influence the actual exposure of a user might differ. But I'm not sure whether there are data in already that addresses this.

DR. KHEIFETS: I thought the technology is different.

DR. OWEN: Well, certainly the technology, for the most, different channels, there's different -- sometimes different ones -- there's different models of phones. There are different schemes --

DR. BOWMAN: Right.

DR. OWEN: -- you know, modulation schemes --

DR. BOWMAN: Right.

DR. OWEN: -- used. But those are fairly easy things to pin down. The things that I was more curious about just offhand were the other things that influence the exposure during use. You know, how -- time used, where used, how held; are you in an urban or suburban environment? what is the density of base

stations? what's the -- it seemed to me that there might be a lot of reasons to --

DR. KHEIFETS: Well, I think that historically it's been much more expensive in this country than in some other countries. I think that the usage has

been behind compared to some other countries.

DR. KACZMAREK: Population density might play a role as well. I mean, most of the European countries are far more heavily populated than the U.S. And that may play a role in terms of things like distance to the base station.

DR. OWEN: Um-hmm.

DR. BOWMAN: I would be willing to bet a dollar that there is differences in the exposure profiles, because the U.S. is following somewhat a different course in terms of, you know, distribution profiles. Also, we're not as densely populated as an average as some of Europe and so forth and so on.

But if you look at it in terms of the health effects, if the -- if the Interphone Study finds an association or the opposite of, would that be any basis for claiming that the health effects would be different in the U.S.?

And I think though, you know, it would be premature to make strong claims, still -- and it would

also be prudent to conduct, you know, software-modified phone studies in the U.S., so that we have some basis for comparison, objective basis for comparison. Still I think those would be quantitative differences and not -- and I'd be very surprised if it would affect the outcome and

health index.

DR. KHEIFETS: Is it too late to join that study with Europe? Has the train left the station?

DR. OWEN: Well, I'm sure because there's a unified protocol that a group could always, you know, could always --

DR. KHEIFETS: But would it be in time --

DR. OWEN: -- be part. But it's not clear whether that we would then be included in the pool, or whatever they're going to call this analysis.

My understanding of the Interphone project is, for the most part, it's a collection of independent projects that will be independently analyzed --

DR. KHEIFETS: -- analyzed.

DR. OWEN: -- and published. But then there's a --

DR. BOWMAN: -- mega --

DR. OWEN: -- a tertiary -- yeah, whatever you want to call the next stage. I mean, I was just grouping them all together.

DR. LOTZ: Based on the fact that they're going to work under a common protocol and a common --

DR. OWEN: So that the data presumably across compare --

25 DR. LOTZ: -- and a common survey

instrument or --

DR. OWEN: Right.

DR. LOTZ: -- or at least an equivalently designed, whether it -- how common it is after all the language translations, I don't know.

DR. OWEN: Yeah.

DR. LOTZ: But it would seem to me that --

DR. BOWMAN: Try translating nylon welder into Swedish.

DR. LOTZ: It would seem to me that it would be, you know, if there were the support for it, it wouldn't be hard to move into that, because I mean there's -- I don't know what it was originally designed in. But there's already a Canadian component and an Australian component and maybe a U.K. component. So there's English language versions of the whole thing --

DR. OWEN: Yeah.

DR. LOTZ: -- exist already. But it's the support factor that is lacking.

DR. OWEN: Yeah. It is important to point out there is a -- we always say Europe. Or we frequently say European. But there is a Canadian component --

DR. LOTZ: Um-hmm.

DR. OWEN: -- and the Australian component. You were saying something, though, Joe, and

I'm not sure I understood it completely. You were saying that it would make sense to have a software-modified phone study in the U.S., that you could compare to the results.

DR. BOWMAN: Yeah. We were talking earlier about the differences between, you know, density of base stations and different transmission protocols and so forth and so on. And, you know, if you're talking about extrapolating the Interphone Study to the U.S., the one thing that you could get data on, easily over, you know, the next couple years when the Interphone Study is going on, would be the software-modified phone.

And so at least there you would have an objective basis to compare U.S. usage patterns with those countries that were in the Interphone.

DR. OWEN: Right. And then when you were saying that before, it sounded to me like you had a caveat, another part, that even if you did have this that allowed the cross-comparability of the exposures, that for some reason there would still be a problem in terms of drawing any conclusions whatsoever on the potential --

DR. BOWMAN: Well, my presumption --

DR. OWEN: -- health effects.

DR. BOWMAN: -- is that there wouldn't --

that there would not be a qualitative difference than the results if the study was done in the U.S. versus Europe.

I mean, there -- I mean there could be a quantitative difference. And, certainly, God knows from ELF, we know that you do a study this complicated in different sites and chance plays a role in how you can be significant in one site and not in the other. And what that means is, of course, always open to interpretation.

But still if in -- especially if in the aggregate they find an association or the reverse, I think the presumption would be that it would apply if it's -- if it is a possible health risk or probable health risk, the same judgment would apply to the U.S.

DR. OWEN: Okay. I was afraid you were saying that was not the case.

DR. BOWMAN: No.

DR. OWEN: And that's why I was --

DR. BOWMAN: No.

DR. LOTZ: Then I guess I -- just sort of

a related thought, I've been kind of, of the opinion that when we were talking earlier about other occupational groups exposed to RF, that if you were to do a study of a different exposure group, not mobile phones, but tower climbers or RF heat sealer workers or something like that, that the information learned from those about the biological effects of RF, I would still, with a little bit of caution, be relatively comfortable in applying that

knowledge gained through consideration of the effects of wireless phones, or the RF from wireless phones. Even though the expo -- I mean, you've got the -- you're dealing with localized exposure from handsets and things like that.

But nevertheless, the effect of RF, whether it's a 10 megahertz RF heat sealer or an 800 megahertz phone, that kind of thing is going to certainly be useful information that's meaningful, not necessarily directly applicable, but valuable enough to be worth going after, even for the phone question.

And I know there's some people who feel like maybe the modulation of a phone is more critical, therefore, it wouldn't be as applicable. But I would -- I would tend to be of the opinion that it would be more applicable than not.

DR. OWEN: And the other end of that, if you were to say that it was not applicable or not useable in the assessment, then you would have -- you know, if you took that to a logical extreme, then you might say, well, you know, GSM information is going to be useless for assessing third generation, you know, and so on.

DR. LOTZ: Yeah. Right.

DR. OWEN: So --

DR. LOTZ: And that's --

DR. OWEN: I mean, one can -- one can have that opinion, but --

DR. LOTZ: Yeah. Well, and, in fact, you know, some of the studies, laboratory studies so far have, you know, have used one or another signal, somewhat with the idea of exploring those kind of possibilities, is that a TBMA signal, a CBMA. There's a variety of different TBMA signals out there, you know, GSM, North American Digital, whatever. And I don't think any of those have come up, certainly definitively showing one modulation or another being -- having a unique effect.

DR. OWEN: Right.

DR. LOTZ: Even the question of digital versus analog, except for the power output, I don't think the studies have been particularly supportive. There's anecdotal information to suggest that there's a difference. But, you know, that was one thing that Swedish/Norwegian Study was designed, that was its primary hypothesis, was to say, is there a difference between digital or analog.

And so of all the information coming out of that, that's the one clear piece that said, no, it didn't support the idea that there was a difference. And that ran counter to their initial hypothesis actually.

DR. OWEN: And it seems like most of those

hypotheses are based more on theoretical arguments than data, than empirical data.

DR. LOTZ: Yeah, I would agree. And that that still holds true after some studies attempting to test the hypothesis, mostly of an in vitro nature.

DR. KACZMAREK: That may be an entire class of symptoms, actually, that's best studied by a laboratory study and not by epidemiologic study.

Basically, if the symptoms is truly subjective, things like headache, and it occurs during the call, the most effective approach would be to study it in a laboratory with volunteers and not through an epidemiologic investigation.

DR. LOTZ: The frustrating part about that, Ron, seems to be that there have now been several attempts in Europe to do that, and at least in the acute short-term, you know, a few -- experimental session of a few hours with some calls, they haven't been able to support -- now, that could mean that there's nothing real to it. But it leaves open the question that somehow repeated use develops these symptoms that a single, you know, single incident can't --

DR. KHEIFETS: How do you blind the person to

25 DR. KACZMAREK: Well, in the laboratory

you have that ability, which you don't have in the context of epidemiologic study.

DR. KHEIFETS: But how do you --

DR. KACZMAREK: In the lab you can do that with a --

DR. KHEIFETS: How do you blind whether you're on the phone or not?

DR. KHEIFETS: -- virtually placebo exposure.

DR. OWEN: They actually can do -- the people have done that where they develop, for laboratory studies, identical looking phones, identical weight, even with circuitry for heating to get the same amount of tissue heating, not only from the insulation factor, but from battery discharge and accounting for -- it turns out the RF heating component is very small compared to the other two --

DR. LOTZ: Yeah.

DR. OWEN: -- heating components. And you can have them both actually attached to a wire.

DR. KHEIFETS: Oh, so you get it through the wire.

DR. BOWMAN: Okay.

DR. OWEN: So they -- some people have

done this in laboratory studies. But, obviously, as I

guess Ron was saying, you could not expect to do that for an epi study.

DR. LOTZ: Yeah, they've been pretty -- I mean, there have been a couple generations of those kinds of efforts where they've gotten more sophisticated about --

DR. KACZMAREK: Right.

DR. KHEIFETS: Have people looked at the, like the memory loss or some cognitive functions or similar --

DR. LOTZ: There have been a few studies of cognitive function with a small number of subjects, in which there have been some statistically significant differences, suggesting there may be some interaction there with brain function. They haven't been deleterious. But they -- they might be -- that there might be some real interaction there.

It's supported by a couple of the studies, at least. I mean, very small, subtle differences, but ones that appear to be reliable in the data.

DR. KHEIFETS: What about reproductive exposures? That has never been an issue in this area at all, right?

DR. LOTZ: Oh, yes.

25 DR. OWEN: RF?

DR. LOTZ: It has.

DR. OWEN: Oh, yeah.

DR. LOTZ: Yeah.

DR. KHEIFETS: Well, I mean with the cell phone use.

DR. LOTZ: Oh, not with the cell --

DR. OWEN: Right.

DR. LOTZ: Only in that we have had -- we have had worker inquiries, even from groups of workers, particularly related more in that case to the two-way radio, the walkee-talkee worn at the hip, from female emergency medical technicians, for example. And so there have been some inquiries.

But there have not been any -- you know, there haven't been any outcry or your major, you know, a lot of -- one of the things we found is that the over -- the whole cell phone awareness publicity has raised questions from other people who are occupationally exposed to RF, more than existed before.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: Now, the workers are definitely out there saying, well, they're talking about cell phones. But I use RF of a different type; what about me?

DR. KHEIFETS: Um-hmm.

DR. LOTZ: And so even where -- you know,

RF heat sealers have been around for decades and were sort of a flurry of activity in the '70s and '80s, about it, and then it kind of died down.

Now with all the interest in cell phones, there seems to be sort of a renewed interest on the part of workers dealing with heat sealers, saying, I use RF too; what about me?

And so we feel like, more or less, anecdotally that the emerging awareness or public discussion of issues about RF generalizes to other people. And that would be the same -- true for reproductive concerns.

DR. OWEN: The other -- there have been data collected bearing on the re productive outcomes for higher level RF exposures.

DR. LOTZ: Oh, yeah. There's actually --

DR. OWEN: It's not a totally unexplored --

DR. LOTZ: And there have been a few studies of, for example, nurses involved in diathermia use

or physical therapy, that kind of thing, medical use of RF where the -- for the occupational person employing those technologies. And a few of those suggest some positive results. So there -- there's a little bit of data out there.

DR. BOWMAN: Isn't it fair to say that the clear positive results are RF exposures high enough to cause heating?

DR. LOTZ: That's correct. And the animal work is very clear in terms of that there can be reproductive effects from RF, territorlogical and so forth, but that they do require those threshold kind of level exposures.

DR. BOWMAN: So those would exceed the guidelines, wouldn't they?

DR. LOTZ: Yes, they would.

DR. OWEN: And I think --

DR. KACZMAREK: Thermal effects, not non-thermal effects.

DR. OWEN: Right. And I think you can go --

DR. LOTZ: Yes.

DR. OWEN: -- further than that, that those levels include deep heating that may not be perceived by the person that exposed -- is exposed.

DR. LOTZ: Yeah.

DR. OWEN: So it's not just heating that they're aware of, but actually levels of RF heating that are high enough to cause a thermal effect --

DR. BOWMAN: And that is one major

difference between the heat sealers and the cell phones, is that the heat sealers at 10 megahertz have a wavelength long enough to cause the deep heating, while the cell phones have very limited skin depth.

So it would be -- even when it's worn on the hip, it --

DR. LOTZ: The penetration of it.

DR. KACZMAREK: It's real questionable what the fetal dose would be.

DR. BOWMAN: Right.

DR. KACZMAREK: If we're going back to the principal of, we should study where the dose is the greatest, fetal dose is unlikely to be substantial.

DR. BOWMAN: Right.

DR. OWEN: Right.

DR. LOTZ: Yeah, that's a good point.

DR. BOWMAN: Another possible situation that I think at least bears a little bit of a look at is these wireless networks where a transmitter is installed in a laptop computer.

DR. KHEIFETS: That's an interesting question. The CTIA has actually inserted internet in their name. So --

DR. OWEN: Yeah, I probed that. And they're not -- it's -- my understanding is that it's not

what -- what first came to my mind is not they consider part of their responsibility, but rather the internet comes from the -- the internet access through the phone, as opposed to wireless LANS or any of these other internet-related functions.

I've asked about that, thinking that there might be a broadened interest, because, yeah, sometimes you do run into -- you could identify something that's very, very interesting and, well, being many of us from the government, we know about jurisdictional lines, you know, not my problem, or something like that. So one can anticipate and understand how that might happen.

DR. LOTZ: Brian, in the work of your group on SAR determinations, have you considered or just even evaluated any of these other devices like wireless laptop transmitters on computers and things like that, to just have an idea what -- how much energy's being irradiated, what's power out, what the SAR might be?

DR. BEARD: The short answer is no. But the standard is written to cover all handheld transmitting devices. So not only will it cover cell phones, it will cover walkee-talkees and FMs.

DR. KHEIFETS: Is computer laptop handheld?

DR. BEARD: That --

DR. KHEIFETS: Or it's lap -- it's lap held.

DR. BEARD: -- again, I think probably becomes a jurisdictional issue.

DR. OWEN: I don't think there's --

DR. BOWMAN: Do you put your laptop on the left or right leg.

DR. OWEN: Now, you know, I'm not FCC. And it's been a while since I read the '96 guidelines. But --

DR. LOTZ: About five years.

DR. OWEN: Well, I don't know. Maybe not quite that long. But I think the main -- the main decision point on those is -- is it 15 inches away, or something? There was -- there was a -- it was mostly based on distance. I don't recall seeing it based on whether it was a handheld or lap mounted or whatnot.

But it's -- and I certainly don't recall seeing any power exclusion clauses for things that would be described as a wireless LAN or -- but there --

DR. LOTZ: Actually, I was thinking there was a -- there was a much lower, than historically in the IEEE power exclusion clause, maybe a hundred milliwatts or something like that?

25 DR. OWEN: Right. I think that was a site

assessment exclusion or something like that where they still had to provide -- I don't know. We'd have to --

DR. BEARD: Yeah.

DR. OWEN: -- call up Bob, Bob Fleet from the FCC, or somebody else.

DR. BEARD: Yeah. I think there was something in there, below a certain level basically it was wide open.

DR. LOTZ: Yeah. And --

DR. BEARD: And I mean, you -- anybody could build something that was below a certain power level, and I think it might have been that.

DR. OWEN: But it was something pretty low and honestly --

DR. BEARD: Yeah.

DR. OWEN: -- lower than the previous low power exclusion, which did encompass wireless phones.

DR. LOTZ: You know, I think it was kind of high enough, for example, to exclude the -- what I'll call the older or traditional model of cordless phone in the home, which I think was about 60 milliwatts of energy out of those.

It wouldn't exclude the new 900

megahertz

ones that run more power, in terms of what was required. And I -- I think because those are at 915 megahertz or

something, they fall into a loophole. But they're not re -- they don't have to have license by FCC or because they're in the ISM band, they don't have to have testing, or something like that.

DR. OWEN: The cordless phones in the home?

DR. LOTZ: Yeah.

DR. OWEN: That's not my understanding from them. But rather that -- from FCC.

DR. LOTZ: But they don't have to do SAR testing on them, do they?

DR. OWEN: Right. But there was -- there was a -- my understanding is that the approach that they took was to come up with reference levels which provided that those devices satisfy. And if you satisfy those reference levels that you're, you know, guaranteed under worst case scenario to satisfy the SAR limits, it's -- it's, you know, like we --

DR. LOTZ: Oh, I see.

DR. OWEN: -- approach using the IGNA

(phonetic) guidelines. You've got the actual restrictions. And anybody can -- that's what you have to comply with, if that were a law. The reference levels are an implementation aid that, if you satisfy those, the idea was, when they were developed, worst case scenario, you

satisfy those, and you're definitely in compliance with the basic restrictions.

But there's a possibility of violating those reference levels. And then all you -- then you're required to do a more accurate assessment to see if you comply with restrictions.

Again, you know, it's a loose analogy, cause those are guidelines, not -- well, though, a lot of places now they're basically law. The IGNA guidelines have essentially become law in a number of countries. So that's the approach as I understood it.

But it is -- it is a continually recurring question; not only what's the exposure assessment problem with the device we think we know about, but the -- every new, not only changes in the technology of that device, but also each new device like the wireless LANS or the, you know, blue tooth, or anything that falls in between.

One thing earlier I was trying to -- I asked a question about what other data would need to be collected so that if down the road you found out that SAR was not the important thing, you know, what information would you need.

And, actually, I asked that because of comments that were made at the meeting a couple weeks

ago,

where somebody suggested that potentially bio-effect, and,

presumably, down the road, a health effect, would be critically dependent not on the SAR, but by some more complex function of the geometry of the RF exposure. And it had a lot to do with the transition between near field and far field.

So that's -- you know, I didn't have a full understanding of the thinking behind that set of comments, but I wanted to throw it out here in case it did ring a bell for, you know, other type of data that needed to be collected.

DR. KHEIFETS: Is the thinking is that we shouldn't put all the effort into the SAR because we don't know, you know, if -- you know, if there was, let's say an ELF effect, there certainly is not going to be a tissue heating effect, it's going to be some aspect of it than that. And so is that the idea that --

DR. OWEN: Yeah. I think the --

DR. LOTZ: Yeah.

DR. OWEN: I think the argument is that we essentially have a circular argument here that, you know, we've identified SARs and dosimetric, which sort of presumes that any effect is a heating effect. But we think we've identified all the heating effects. And so you sort of usually exclude --

DR. LOTZ: What I -- I guess where I

thought you were going, because SAR is related to electric field strength in the tissue, the idea that it's only related to a heating effect doesn't seem to me to be valid, that it's -- it's a bonafide metric, whether or not there's heating, as long as we're talking about relationship to the induced electric field. Cause that can be true even down at very, you know, very small levels, very low levels.

But the other side that the SAR can't, clearly can't cover, is if things are uniquely dependent on the modulation, because that's a -- that's an aspect of exposure that's not going to be captured by an average electric field intensity, no matter what.

DR. BEARD: And that is -- that is a point. It is an average, because the SAR is time and spatially averaged.

DR. LOTZ: Um-hmm.

DR. BEARD: So, as you said, it can't capture modulation. It also can't capture peak power, which is why I had mentioned peak power before, because the average can totally obscure the peak.

DR. KHEIFETS: Well, I mean, I think that it just says that when you collect data, you have to be a little bit broader and, you know, collect data on the

relevant -- you know, especially if you don't know, you

know, what the dosimetric is, that's -- well, you're not sure what the dosimetric is, you know, then you're sort of stuck with surrogates. And sometimes a surrogate is better in that situation, just because you -- you know, it allows you to be broader and not so specific, which is generally a weakness.

But in situations where so much is unknown, it might be a good sort of sanity check. Just if something pops up with something else, then you know you're going down the wrong valley here SAR.

DR. LOTZ: And, Leeka, you're right in, I think, you know, there's another comparison to the ELF history is that we don't really know the metric. If there, in fact, are effects related to long-term use, then we're probably dealing with a metric that we don't understand at all in RF, just as in ELF we're confused

about the metric.

You know, yes, in RF, there are clearly effects of short-term use that we tend to understand are probably related to heating. But that's not going to be the case if there's these long latent delayed effects.

DR. OWEN: Yeah. Actually, the pace that you said about collecting peak power to dosing -- like an important one that you might have missed, if you were only -- if you were really too focused on SAR. The modulation

specific questions seem like they might be fairly easily captured by specifying, you know, which technology is being used, because that's -- because of the -- you know, the nature of the beast is, there's -- a standard has to be used in order for the different phones to --

DR. BOWMAN: Right.

DR. OWEN: -- all communicate, you know, within the network. And so as long as you do collect the information about which model of phone is being used and under which modulation scheme, it seems like you would be able to sort of reconstruct or deconstruct, whichever would be the better word, these other unknown metrics that might be better than SAR, as long as you have that peak power number in addition to everything else that we talked about.

DR. BOWMAN: Right at the moment, I would -- my -- the way I'm envisioning the analysis in the

Interphone data is that in the software-modified phone study, we'll get proportionate time that they're operating in the different transmission modes, and as a function of the locality and the service provider.

And we would basically make the presumption, at least for one level of analysis, that could be applied to the subjects in retrospective fashion.

And then -- so the proportional time each subject spends

in the different transmission modes would be a co-factor in the analysis along with the energy absorbed.

And that would be the way to test the hypothesis that, you know, that does or does not effect the association, if there is one to begin with.

DR. OWEN: Like the potential ELF specific effect might be best captured by the surrogate, as you were saying, as opposed to any of the other more sophisticated measures, if there were one.

DR. KHEIFETS: It's just if it's unknown, I mean, I -- I don't know. There's -- I think that the ELF data could be used in several ways. But one of them is, if there's something there, you know, it would be very hard to understand why there wouldn't be any -- anything else anywhere else, I think, 16 hertz. Frequency is a special one aside.

You know, I -- so, you know, so I think that the thinking just has to be sort of broader than just focusing on that, because we certainly know that there is no tissue heating of that level. That's -- it's kind of

--

DR. OWEN: You mentioned earlier a published study that you guys had on the ELF exposures from wireless phones.

DR. KHEIFETS: Um-hmm.

DR. OWEN: What was the --

DR. KHEIFETS: It wasn't really on the ELF exposure of wireless phones. It was just trying to see how well people recall what they do and how well you could -- I mean, the idea was just to -- how -- what kind of data you can get by the questionnaire. How good is the data?

DR. OWEN: Okay.

DR. KHEIFETS: By questionnaire, just cell phone was one of the things that people used, or one of the, you know, appliances. But the idea is, can you develop a questionnaire by which you could sort of ascertain overall where the exposures were. And as part of that study, and also by a person recalling his own exposure recently and recalling his own exposure ten years ago, and then by his partner recalling the same stuff on the question. So they were kind of the proxy for each other.

And I'm trying to evaluate how much of the

exposure you could capture, both occupational and appliance use, you could capture through the questionnaire. And then they also wore meters for, I don't remember, like a day, a week, whatever, some period of time. And so then we tried to also correlate the information on the questionnaires to the information -- to

the exposure range. Just a large component of exposure was cell phones. That was -- that was really not designed to look at the cell phone use particularly.

DR. OWEN: I'll reach back again to the meeting a couple weeks ago for another one to put on the table. There was mention, potential utility, of looking at doing -- studying registries for particular endpoints. Maybe Abiy, you can remember more specifics about that one, or Greg.

It was a -- it was a -- somebody suggested the possible utility of looking at registries for endpoints that had a relatively stable incidents, I believe is the way it was described.

MR. DESTA: I think it was Moulder who raised that question, see if there was a rise in the last ten years or so, when cell phones became primary sources of --

DR. KACZMAREK: Well, certainly, it's certainly worthwhile to look at the SEERS data regarding brain and nervous system cancer incidents. But I think

we've already discussed that. Again, that incidents was 6.5 per hundred thousand, on an age-adjusted basis in 1990. And the latest available data from 1998, is only 5.8. So it clearly has not increased.

But we need to keep following that, you

know, into --

DR. OWEN: Yeah.

DR. KACZMAREK: -- the future for --

DR. LOTZ: Yeah. I was thinking it was actually Peter Inskip that brought that up. But I'm trying to think whether there was something more specific to it. Whether he was talking about -- he'd been trying to look at a particular sub-population or something. I can't recall the details of that.

DR. OWEN: Well, I think --

DR. KACZMAREK: Well, certainly, in Scandinavian countries where you have registries that include the entire population -- I mean, that's how Johansen's study was actually done. They looked at subscribers in terms of exposure assessment. But the endpoint, the cancer incidents was assessed with the Danish Cancer Registry.

So in those countries, I mean, there would be considerable merit there, when you -- determining your endpoints by basically having the exposed people all on a computer in the registry.

DR. OWEN: I guess Mary McBride mentioned, after -- later in that meeting, that she thought that there might be some other registries; you know, nothing

nearly so big and well known as the SEERS data, but some

other registries that might be mined for this kind of work.

DR. KHEIFETS: But you have to be very, very careful. I mean, you'd only capture that way, a really huge problem. I mean, you would not be able to --

DR. LOTZ: Well, and that was discussed that it was, at best, just maybe a screening tool to say, okay, if there's something there, then --

DR. KHEIFETS: Yeah, that's --

DR. LOTZ: -- maybe we ought to go look at it.

DR. KHEIFETS: That's fine. I mean --

DR. KACZMAREK: But it's not really a complete study in itself.

DR. LOTZ: No.

DR. KHEIFETS: It's just -- I just know that this kind of data has been used, or I should say abused, in an inappropriate way. And I just, you know, no sense going through that exercise again, you know, plotting the rise in use of power versus total accumulative rates, and then plotting, you know, use of benzine. Again, that's not the same plot, you know. And all this kind of stuff. So it's just -- it's not a usable exercise.

DR. OWEN: And I guess part of the context

of that came up with -- came up in was that such studies were quite inexpensive and easy to do. But there was some --

DR. KHEIFETS: Yeah. Ron just --

DR. OWEN: -- discussion on --

DR. KHEIFETS: Ron just did it for you.

DR. KACZMAREK: Right.

DR. KHEIFETS: I don't know what it cost you. Five dollars maybe. He just did it from 1990 to '98.

DR. LOTZ: It cost him the price of the trip out here.

DR. KHEIFETS: So you can update that on a yearly basis by bringing Ron over.

DR. OWEN: Check's in the mail.

DR. LOTZ: You can't be accused of taking him to too exotic a place.

DR. OWEN: I hesitate -- there's a big can that I'm thinking about opening.

DR. KHEIFETS: Or saving it for tomorrow?

DR. OWEN: Well, no. I was actually thinking of saving it for 15 minutes to give people a chance for a short break.

DR. LOTZ: That would be a good idea.

DR. OWEN: So how about a quarter after,

and then I'll open that one --

DR. KHEIFETS: Okay.

DR. OWEN: -- and see if we can kick start a conversation.

(BREAK - 2:58 to 3:23)

DR. OWEN: I promised to open up a can of worms when we got back together. I've been holding off. One of the things that happened in a meeting that we had a couple weeks ago was that we very quickly jumped to discussing, at great length, cohort studies and the need for cohort studies and some of the questions of exposure -- a lot of the questions were exposure assessment in the context of the cohort studies.

And so it's interesting how the track of this discussion has been quite different. But I thought I'd go ahead and just introduce the general topic of cohort studies and possible needs in that area. Not because it's necessarily a follow-up to, you know, the Muscat case control or anything, but largely because it was discussed so extensively in our earlier meeting.

And again, as I said at the beginning today, certainly any of the RF, epi discussions are within the scope of the kind of input that would be useful to come out of these.

DR. KACZMAREK: Well, there's certainly

merit in a cohort study here. For openers, you don't have the same strengths and weaknesses in a cohort study that you do in a case control study; we call bias, which is often a major potential, at least a potential problem in case control studies is just simply not a problem in the context of a cohort study.

Secondly, a cohort study --

DR. BOWMAN: For the prospectus point.

DR. KACZMAREK: Well, no. But you don't have the same problem in terms of the cases recalling their exposure and in different manner, a different fashion as opposed to the controls. And that's what I'm referring to specifically. My definition of recall bias, it's just human nature that the people who have, actually had the disease of interest may recall their exposure in a somewhat different fashion --

DR. BOWMAN: Oh.

DR. KACZMAREK: -- than controls might.

DR. KHEIFETS: You're assuming that the cohort study is not based on the questionnaire, but based --

DR. KACZMAREK: Right.

DR. KHEIFETS: -- on some other records that they're not individually driven; otherwise retrospective cohort would have --

DR. KACZMAREK: Right.

DR. KHEIFETS: -- the same problem.

DR. KACZMAREK: Sure.

DR. BOWMAN: So go ahead.

DR. KACZMAREK: Yes.

DR. KHEIFETS: Yeah.

DR. BOWMAN: I didn't --

DR. KACZMAREK: Okay. Certainly, in the context of a prospective cohort study, you don't have the same problem. But also, as well, you can look at multiple endpoints in the context of a cohort study. And again, you know, for example, the Johansen Study looked at salivary gland tumors. It looked at leukemias. It looked at all-cause mortality. It looked at brain cancers.

So if you have a cohort study, you have the ability to look at many different endpoints; whereas, with a case control study, you can look at many different exposures. I mean, I think there's considerable potential here, that if there's further case control study work regarding brain cancer, we might learn more about the etiology of brain cancer. And there's a clear need to do that, because there's not, at the present time, you know, complete identification of possible risk factors. But you can only look at one disease at a time.

25 So when you have the cohort, you can look

at multiple disease endpoints. And that really does make a strong case for assembling a cohort that can be studied. The downside is that cohort studies are inefficient for studying rare outcomes. And there needs to be recognition of that.

DR. KHEIFETS: Not only that, but the exposure assessment cannot be equally detailed for the full cohort. So you'd have to go to some sort of two-stage design to really --

DR. LOTZ: Right.

DR. KHEIFETS: -- do a comprehensive exposure assessment experiments.

DR. BOWMAN: So that the nested case control design helps address the efficiency issue. But one additional advantage is that selection bias is not quite as problematic with the cohort as it is with case control, because you have -- you're starting with a set sample frame. And to the extent that you can have a quality in locating people and listing their participation, you're not going to have the same kinds of problems that you had with random digit dialing in a straight-up case control study.

DR. LOTZ: Joe, let me follow up on that a second. And that was that -- I've actually heard this

expressed. If you were to set out and do a case control,

prospective case control study, and you're recruiting subjects, would you feel at all at risk that somehow you would get a skewed response or a skewed population in terms of who would respond to say, yeah, I want to be part of that study?

DR. KHEIFETS: Well, you can't -- there is no such thing as a prospective case control study.

DR. LOTZ: I didn't -- I misspoke.

DR. KHEIFETS: Okay. Okay.

DR. LOTZ: I mean cohort.

DR. KHEIFETS: Okay.

DR. LOTZ: Sorry.

DR. KHEIFETS: Okay.

DR. LOTZ: I didn't mean --

DR. KHEIFETS: I mean, some people use --

DR. LOTZ: I do know that -- I do know that much --

DR. KHEIFETS: I know you knew. But I just said that because --

DR. LOTZ: I just got my --

DR. KHEIFETS: -- some people use that terminology --

DR. LOTZ: No.

DR. KHEIFETS: -- for a prospective rapid

case ascertainment.

DR. LOTZ: No, that wasn't what I meant.

DR. KHEIFETS: And I was just trying to --

DR. LOTZ: No, no. I just didn't even notice that I twisted my words around there.

But in a prospective cohort study, just the question of who it is you're recruiting and is there concern there that you'd somehow --

DR. BOWMAN: Oh, yeah. You can't -- I mean, you still have to have them agree to participate, if you are going to do anything more than get --

DR. LOTZ: Right.

DR. BOWMAN: -- their phone records. And given a legal case, you're even going to have to get them to agree to participate if you're using phone records.

DR. LOTZ: Yeah.

DR. BOWMAN: So, yes, you would have to take a look at what the demographics of the people that refused.

The good thing is that you have them enrolled to start with. So you have a sampling frame. And so it's more definitive to look at those things. And it alleviates the problem of identifying them in the first place and making sure that you have a -- you know, with random digit dialing, who answers the phone? who do you

talk to? That kind of thing is skewed. And that source

of bias, you don't have.

DR. KHEIFETS: But you also could have a differential loss to follow up.

DR. BOWMAN: Right.

DR. LOTZ: Okay.

DR. KHEIFETS: Which would be a problem.

DR. LOTZ: Right.

DR. KHEIFETS: So in addition to your recruitment thing, is -- you know, let's say people who use cell phones a lot get offered jobs a lot, move out of the area a lot or something. I don't - you know, so you -- I'm just making up a --

DR. LOTZ: Yeah.

DR. KHEIFETS: But there could be a differential loss to follow up, which could be a problem as well.

DR. KACZMAREK: With a cohort study, fundamentally, the disease of interest has not yet occurred. You simply have to wait for that to occur. And while you're waiting, people can totally be lost in the process. It's an issue you don't face in a case control study, because the disease of interest has already occurred in your cases.

DR. KHEIFETS: Why did you call it the

can

of worms?

DR. OWEN: Because it's -- because in the previous meeting it caused so much discussion and it was difficult to get discussion going on --

DR. KHEIFETS: I see.

DR. OWEN: -- the case control studies that were the, you know, sort of at least the reason for calling the meeting.

DR. KHEIFETS: Well, I mean, I --

DR. LOTZ: Well, and I guess -- but there was a related question that I don't -- and maybe to put it sort of in the parking lot for making sure we address. And that was, for example, is the IARC Study potentially definitive enough that we don't need to do something else?

DR. KHEIFETS: Of course not.

DR. KACZMAREK: No.

DR. KHEIFETS: There's no such thing as a definitive study.

DR. LOTZ: Okay. But in actuality, I think it's, in some respects, it's being described that way.

DR. KHEIFETS: Well, you could --

DR. LOTZ: It's going to be so large. It's going to be multi-national. You know, that this is going to give -- certainly in the newspapers --

DR. KHEIFETS: Right.

DR. LOTZ: -- it's been described that way, that this will give us the answer. And we'll have to wait five years for it, but then we'll know.

DR. KHEIFETS: And then after --

DR. OWEN: You could pose a similar -- or maybe the same or a similar question far less provocatively, by saying, does the IARC Study address all the case -- all the, you know, most important case control needs for the moment? You know, something a lot less --

DR. KHEIFETS: Meaning, does it address that one particular outcome? Or what do you mean by important case control needs?

DR. OWEN: What's needed --

DR. KHEIFETS: Brain cancer?

DR. OWEN: You know, what's needed and how important is it?

DR. KHEIFETS: Well, I mean, I think that given the -- given the tremendous exposure or prevalence of exposure in the population, and given how little is known, you know, having a cohort that's followed up is

always a good idea.

I think that just having that cohort established is good. That's not -- but I think that's not going to be enough. I think, in addition with that cohort, you need to do some ongoing exposure assessment

studies that kind of describes the state of, you know, with small samples from the cohort or whatever. However you wanted to do that to just provide you all kinds of baseline data that you might need later.

And then -- and then depending on what develops, then you might need to follow up whatever findings from the cohorts are, will be much more detailed as to case control studies.

So, I mean, I don't think -- I mean, from my perspective, it's not particularly a can of worms.

DR. OWEN: There was other -- one other reason that it would be a can of worms; and that is the potential price tag.

DR. LOTZ: The long-term commitment and price tag I think --

DR. OWEN: Yeah.

DR. LOTZ: -- were in the previous session. There was sort of a big gulp in the room, I think, about that.

DR. KHEIFETS: It's a big industry, isn't it? I'm not very sympathetic with those kind of --

DR. OWEN: Oh, yes. It's not coming out of our appropriated budget. So I'm not sympathetic.

DR. KHEIFETS: No. I mean, I don't know.

It's -- so, yeah, it's only money.

DR. LOTZ: Yeah. It represents a mind set. Is it, you know --

DR. KHEIFETS: Yeah.

DR. BOWMAN: Another --

DR. LOTZ: If you look at it --

DR. BOWMAN: -- can of worms is the legal case. In both the Danish situation, as well as the Rothman rejected cohort, we were going to use phone records to establish the cohort. And to what degree has the legal problems that Rothman's efforts ran into, made that problematic to even get it off the ground.

DR. LOTZ: The situation I think there mostly revolves around the fact that they were not going to contact the individuals at all and get any voluntary consent.

DR. BOWMAN: Right.

DR. LOTZ: So if you approach it from the standpoint of we'll actually recruit and enlist people with voluntary consent, then you can beat the legal problem in this country with a new effort.

DR. KHEIFETS: Based on their phone numbers and addresses or something, right?

DR. LOTZ: Yeah.

DR. KHEIFETS: Somebody has to release some information.

DR. OWEN: You need their Social Security numbers to compare them to the National Death Index. I mean, that was --

DR. KHEIFETS: Right.

DR. OWEN: -- what was concluded in the Rothman Study.

DR. LOTZ: Yeah. But you could -- you potentially could recruit them almost through open advertising and things like that.

DR. KHEIFETS: Then you have to be very selective.

DR. LOTZ: Well, that was why I raised that question earlier. How do you go get them? But in the sense that there is now such a large population of users that you probably could get consent, volunteers even of a large cohort, to --

DR. BOWMAN: To get active responses from volunteers to a passive solicitation, I think you'd be lucky to get 10 percent of the cohort, and it would be a very skewed --

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: -- population. I think to really have much of any chance of success, you really want to actively recruit people based on at least their phone numbers.

DR. LOTZ: Well, that's certainly a fair consideration in terms of --

DR. BOWMAN: Now, whether that would run into problems or not is --

DR. KHEIFETS: Well, you could -- I mean, you do random digit dialing.

DR. BOWMAN: But then you're back to --

DR. KHEIFETS: Can they tell -- can one tell just by the phone whether it's a cell phone or not? Is there a way -- does anybody in the, whatever, world, whatever --

DR. BOWMAN: If you get the records of a cell phone service provider --

DR. KHEIFETS: No, no. Well, yes.

DR. LOTZ: I'm even thinking that --

DR. KHEIFETS: But just by looking at the phone --

DR. LOTZ: I'm even thinking that certain --

DR. KHEIFETS: -- is there a way to tell that it's a cell phone?

DR. LOTZ: -- exchanges are cell phone.

DR. KHEIFETS: Well, that's what my question is. Is there a --

DR. OWEN: Yeah.

DR. LOTZ: I think they've generally established a new, say --

DR. KHEIFETS: So if it's like 323, that means it's a cell phone, whatever, you know.

DR. LOTZ: I don't know whether anybody in the room can answer that question. But that's my sense of what's going on around here was, as I see certain numbers popping up as --

DR. OWEN: Yeah.

DR. KHEIFETS: Well, if that's the case, then it's very easy to --

DR. OWEN: Yeah, I think it's pretty easy..

DR. KHEIFETS: -- start, you know, just --

DR. BOWMAN: Dial them all.

DR. KHEIFETS: You know, you're just --

DR. BEARD: Somebody on the IEEE Committee

that I'm on suggested manufacturers package an informed consent form with each new phone.

DR. BOWMAN: You're still looking at active response to a passive solicitation.

DR. KHEIFETS: Yeah.

DR. LOTZ: You made a comment a moment ago, Joe, that that would not get you the population you'd really want. And that's because there'd sort of be some

bias in terms of the people who would be most --

DR. BOWMAN: Oh, right.

DR. LOTZ: -- be interested in doing that.

DR. BOWMAN: Right. Yeah.

DR. KHEIFETS: Well, it wouldn't be a bias. It would be a question of -- I mean, theoretically, if you just get -- I mean, ten percent is extreme. But you have a small participation rate. And if it's a prospective cohort, probably you should be okay with internal comparisons. But it's just, is that group going to be generalizable to --

DR. KACZMAREK: -- to the rest of the population.

DR. KHEIFETS: -- the rest of the population.

DR. OWEN: Be representative.

DR. KACZMAREK: Right.

DR. KHEIFETS: -- is going to be more of an issue.

DR. KACZMAREK: Representativeness is a huge issue.

DR. BOWMAN: I was just thinking in terms of, instead of random digit dialing, do uniform digit

dialing. If your computer's dialing the phone, you know --

DR. KHEIFETS: Well, that's what I meant, yeah. It's going to be very hard, I mean, no matter what you do. Whether you go case control cohort or whatever, it's just going to be -- it's going to be very hard. I mean, it's a very hard exposure.

DR. KACZMAREK: Well, case control has the advantage you just have to recruit fewer subjects.

DR. LOTZ: Right.

DR. KACZMAREK: I mean, a sample size in the hundreds for case control is going to work. I mean, hundreds of cases and hundreds of controls. For cohorts, I mean, we're talking in the hundreds of thousands.

DR. OWEN: Particularly for rare disease endpoints.

DR. KACZMAREK: Right.

DR. OWEN: I'm sorry. Now, I have a question. Uniform versus random digit dialing.

DR. BOWMAN: Well, random digit dialing will --

DR. OWEN: I think I understand the random.

DR. BOWMAN: Well, the computer selects numbers by random number generator and you continue until you have the number of controls you want.

DR. OWEN: Right.

DR. BOWMAN: With uniform digit dialing, I'm thinking you want everybody with a cell phone.

DR. OWEN: Oh, okay. I see what you mean.

DR. BOWMAN: So let the computer, you know, dial away until you actually get somebody to answer and let the --

DR. OWEN: Where you only randomize the last four digits or something.

DR. BOWMAN: Right.

DR. OWEN: Right. Okay.

DR. BOWMAN: And when the system comes back and says, this doesn't exist, you throw it off the list. If it's busy or, you know, not -- the person doesn't have their phone activated, you put it in to a pile to keep recycling. And you let the computer crank away with people on the other end to request participation.

DR. KHEIFETS: But certainly having the first three digits, which were assigned, that can't be a confidential information. I mean, it could --

DR. BOWMAN: Right.

DR. KHEIFETS: -- be only confidential information from the perspective of the companies.

DR. BOWMAN: Right.

25 DR. KHEIFETS: But it's not confidential

information from the perspective of any individual.

DR. LOTZ: Right. And once you make the contact, then you enlist them.

DR. KHEIFETS: That's right.

DR. LOTZ: And so you got their consent anyway, to whatever. I mean, that's part of your opening --

DR. KHEIFETS: Right.

DR. LOTZ: -- contact, is, would you be willing to do this and give us these records or whatever.

DR. KHEIFETS: Right. Right.

DR. BOWMAN: And there would still be a systematic bias toward the people that have their cell phone on a lot than people who don't have their -- you know, just turn on their phone because they, you know, want to make a call, you would be very unlikely to get contact.

DR. LOTZ: That's true in that, yeah.

DR. KHEIFETS: Yeah. But, again, that would be a question of just sort of external validity, not internal validity.

DR. LOTZ: Well, in --

DR. KHEIFETS: You'd kind of be comparing people who have their phones on a lot to those who have

their phones on a lot within the RTEO, try to see the

difference of the use or something like that. So --

DR. BOWMAN: Right. Right.

DR. LOTZ: And this is my own ignorance. In the cohort study like that, would you try and recruit a certain number of non-users? Or have people who might then give you -- I mean --

DR. BOWMAN: Well, to get non-users, you have to establish a different sampling frame.

DR. LOTZ: Um-hmm.

DR. BOWMAN: What we were talking about either using billing records or other kind of phone company records, or this uniform digit dialing, you'd be focusing on the three digit prefixes that are cell phones.

DR. LOTZ: Right.

DR. BOWMAN: Now, you can go to non-cell phones while you're at it, if you like. But I'm not sure what the epidemiologic reason for that would be.

DR. LOTZ: Well, I guess if you wanted any non-users or, you know, sort of --

DR. OWEN: Or to --

DR. BOWMAN: Yeah, a not-exposed group.

DR. OWEN: Right.

DR. LOTZ: That's what I'm thinking.

DR. KACZMAREK: Right.

DR. BOWMAN: Um-hmm, yeah.

DR. KHEIFETS: I think it would probably --

DR. BOWMAN: That sounds useful to me.

DR. KHEIFETS: Well, I think -- yeah. But I mean, you probably will --

DR. LOTZ: I mean, obviously, you can --

DR. KHEIFETS: -- have such low users anyway, so --

DR. LOTZ: I was going to say, if you can reach them, you would partition the users anyway into --

DR. BOWMAN: Well, right. With the, you know, the --

DR. LOTZ: The uniform --

DR. BOWMAN: -- other cohorts, you'd partition people by their usage or other individual exposure.

DR. KHEIFETS: If you go to a different enlistment scheme, it's just going to be -- then you have a problem of a different SES type of --

DR. LOTZ: Um-hmm.

DR. KHEIFETS: -- you know, a lot of things are going to be different about that group who never uses cell phone, let's say, or something like that.

DR. BOWMAN: Never owned a cell phone.

DR. KHEIFETS: Never own a cell phone,

yeah.

DR. KACZMAREK: Right.

DR. KHEIFETS: So it's --

DR. LOTZ: So better just stay with --

DR. KHEIFETS: Probably, yeah. Probably this right now is good enough. But, I mean, at some point in time, when everybody starts using it a lot, I mean, then that might not be good enough anymore. I mean, you might not have a good comparison.

You want to have a maximum range of exposures, you can. I mean, basically, you can focus on the extremes of the exposure. And you want to separate people with low exposure from people with high exposure and everybody in between is just going to confuse the picture, more or less.

So how you identify more of a separation you get, the more chance you'll have to really see something, I think.

DR. OWEN: Yeah. I guess it would take a lot of -- and it might take some piloting too, to get a rough estimation of what range in exposure you can shoot for without bringing in too many SES confounding issues --

DR. KHEIFETS: Right.

DR. OWEN: -- that might automatically

25 occur if you just went for the heavy users versus the --

DR. KHEIFETS: Right.

DR. OWEN: -- might-not-even-own-a-phone people. There must be an in between.

DR. KHEIFETS: Right. Right.

DR. LOTZ: Yeah, I think you would be --

DR. KACZMAREK: Well, you can adjust for the effects of SES in your analysis, though. I mean, you just have to be aware of it.

DR. OWEN: Well, I was just thinking that we were using SES as an example --

DR. KACZMAREK: Right.

DR. KHEIFETS: Right.

DR. OWEN: -- of the kind of confounder that might occur then. But there might be other ones that we wouldn't know how to adjust for.

DR. KHEIFETS: Right.

DR. LOTZ: I would think if you can -- if you recruit them -- and Joe raised the question whether they -- you know, if they never use their phone, they won't answer that number. But my impression is, there's probably a lot of people out there with a cell phone who use it very little. So that if you could get them recruited in, you would be able to have your range of exposure considerations within people who own a phone.

DR. BOWMAN: And --

DR. OWEN: There's a larger population to call from to get those low users, at least at this point --

DR. LOTZ: Yeah.

DR. OWEN: -- you're saying?

DR. LOTZ: Right.

DR. KHEIFETS: Yeah.

DR. OWEN: So the fact that you can't get them as efficiently, maybe, as you could get the high exposure people, gets washed out by the fact that there's a lot more of them to pick through.

DR. BOWMAN: In the Inskip Study --

DR. LOTZ: Well, even if there wasn't more, I mean, you might have to invest more effort to recruit them, but --

DR. OWEN: Yeah.

DR. BOWMAN: Here's the distribution in the Inskip Study of average daily use. 625 never really use; less than three minutes per day, 53; three to fifteen minutes, 64; more than fifteen minutes, 51; more than sixty minutes, 24.

DR. KHEIFETS: So this is cases?

DR. BOWMAN: Controls.

DR. LOTZ: So other than the -- the

rarely

25 used was pretty big. But then the rest of them were kind

of equal.

DR. OWEN: Kind of equal, yeah.

DR. KHEIFETS: Well, they built it that way.

DR. LOTZ: That's why they divided that way, yeah, right.

DR. OWEN: But what were the cutoffs again, the minutes?

DR. BOWMAN: Less than three, three to fifteen, greater than fifteen per day.

DR. KHEIFETS: Those numbers are probably changing very quickly.

DR. OWEN: Um-hmm.

DR. LOTZ: It's interesting, although the study was probably designed about the same time, I think those are pretty similar to the cutoffs that were used in the study of non-cancer endpoints.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: I mean, that's just where people -- where it breaks out. Some people just use it real, you know, under -- less than five, fifteen.

DR. OWEN: It is interesting, though,

because that would suggest that it's, you know, a contrary finding to the presumption that there's earlier penetration and higher use in the Scandinavian markets

than here. Right?

DR. LOTZ: Well, you still have the percentage of the population that --

DR. OWEN: Yeah.

DR. LOTZ: -- owns one is still a lot higher there. Whether maybe --

DR. OWEN: So you're saying the variability might only be in the non-user part of the population.

DR. LOTZ: Yeah, the --

DR. OWEN: But once you become a user, you're still going to stratify --

DR. LOTZ: The profile of how much you use it might still be rather similar across the different countries.

DR. OWEN: It could be just a simple measure of the degree to which there's a suppressed urge to communicate that instantaneously in the population.

DR. LOTZ: Or it could be --

DR. KHEIFETS: Or how cold it is in Sweden.

DR. LOTZ: Or it could be socioeconomic of

how many minutes can you afford. I don't know.

DR. KHEIFETS: Are you limited to the U.S. in terms of with studies?

DR. OWEN: We can talk about anything we want to talk about.

DR. KHEIFETS: Well, I understand that. But there's no sense of talking about it --

DR. OWEN: And strictly speaking, absolutely not, because if there's an identifiable scientific need, then that's not going to be, you know, seeing borders. In fact, that's something that we've had to talk about a lot. Because people, you know, when they talk about, say laboratory studies, you know, there's no particular reason to think it should matter.

Although, you know, you get into the specifics. I mean, you know, the SD rats that are obtained in Germany are different from the SD rats that you get here. But that's kind of a -- that gets into the minutia of the differences.

Clearly, you know, again going back to possible significant differences in exposure assessment, there might be a reason to focus on U.S. for the purposes of being able to compare to data already available or that will be available elsewhere. But in general principle, no, there's not any requirement.

And, in fact, it runs back in -- as I

mentioned earlier, we, or at least I, frequently make the mistake of sort of breaking everything down between, you

know, U.S. versus Europe. You know, there are other user populations. And, you know, Canada is one that's in the Interphone Study. And, you know, to the American group, whether they're like U.S. American users or what, I don't know.

DR. BOWMAN: Well, certainly in terms of adding information beyond the Interphone Study, if it were just in the U.S., you wouldn't have any concrete basis for comparing -- you know, I mean, you could make rough comparisons. But you don't have any -- this is what we found in the Interphone Study and this is what we found in the cohort study, to make a direct comparison of the same country.

So if you were to do a cohort study, it would seem to me that it would have some rationale to also include one or more countries that's in Interphone.

DR. OWEN: If you were able to, in isolation, in great detail, define the presumptive differences between exposures of American users versus non-American users, is there another reason why that would

be the case, the thing that you just suggested may be the case.

DR. BOWMAN: Well, it's hard for me to, you know, say for sure to rule it out. I just know the direct empirical comparison is always more convincing than

having to make assumptions and extrapolations.

And back to my earlier comment. You know, we should be able to take the Interphone results and apply it to the U.S. But, certainly, there'll always be questions until you're able to make a direct comparison. And likewise, if you did a cohort study and you had better methods in some ways, if you find something significantly different from the Interphone results, disentangling where that's coming from will be harder if you're comparing U.S. with the Interphone countries than if you were able to make an apples-to-apples comparison.

DR. KHEIFETS: Would it be more helpful if we just talk about sort of that, you know, these exposure assessment studies as a beginning and piloting the work that would lead, potentially, to that kind of study.

DR. OWEN: Don't worry about whether it's palatable?

DR. KHEIFETS: No, I mean --

DR. OWEN: Just offer the, you know, offer whatever you're --

DR. LOTZ: Actually, my thought --

DR. KHEIFETS: Well, I mean that from --

DR. LOTZ: -- Leeka, would be that if we think it's useful to do, it's better to say so than worry about what's --

DR. OWEN: Yeah, don't try any --

DR. KHEIFETS: But I mean, the other part of it is that the truth is that we don't know all the ratios. And they really need --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- to be piloted. So, I mean --

DR. LOTZ: Well, it's okay to talk about kind of a staged --

DR. KHEIFETS: Yeah.

DR. LOTZ: -- type thing too.

DR. KHEIFETS: I mean, you know, because a lot of those issues are -- need to be tested. And, you know, the same thing like when they jump into the record stage. Have that been ever tested? I mean piloted. Has anybody looked whether the records reflect persons used and all this sort of --

DR. LOTZ: That same research group did a -- they did publish a couple papers. And they -- in other words --

DR. KHEIFETS: Rothman's group?

DR. LOTZ: -- they did some -- Rothman's group --

DR. KACZMAREK: Right.

DR. LOTZ: -- did some piloting work.

DR. KHEIFETS: They did. Okay.

DR. OWEN: Yeah, for -- and their hand in this --

DR. KACZMAREK: That there was merit in building records, right.

DR. OWEN: -- in fact was one of --

DR. KACZMAREK: Yes.

DR. OWEN: -- the things they did look at.

DR. LOTZ: Yeah. They got that far and then began the actual cohort study, and that's when they got stalled.

DR. OWEN: In fact, they did the -- they even published the overall mortality, you know --

DR. LOTZ: Right.

DR. KACZMAREK: Yes.

DR. OWEN: -- which was part of that pilot work.

DR. KHEIFETS: Um-hmm.

DR. OWEN: But now, I guess all I was

trying to say was, I'd like not to talk about the political --

DR. KHEIFETS: When you did say cost --

DR. OWEN: -- facets or -- hmm?

DR. KHEIFETS: But you did say cost made everybody's jaw drop. And, you know, so that's what I

mean, that --

DR. OWEN: Yeah. But we limited the discussion of that.

DR. LOTZ: Is it -- in the case -- in the sense -- in the terms of a cohort study, is it urgent to get started because you've got to look for so long, better to wait because we haven't had that long a use so far?

DR. KHEIFETS: Oh, I think it'd be urgent to get started because --

DR. KACZMAREK: Right.

DR. KHEIFETS: -- you have to setup the cohort to start to -- you know, the earlier -- I mean, records get destroyed, you lose information, technology changes all of those things. So I think you would have to get started and, you know, not necessarily -- I mean, you could have a detailed plan as to at what point you will do the analysis and not say that we're going to analyze it every year and see what pops up.

You know, but you do some exposure assessment. You do the methodological work. You try to, you know, understand the cohort in a variety of way to make sure that, you know, you're capturing everything you need to capture.

But, I mean, there probably should be

specific analysis plan if one was undertaking something

like that, sort of designing at what point, you know, you would do a certain analysis, because the amount of information is going to be incredible. And then to try to distinguish between, you know, false positives and statistical abnormalities and all of that is always very hard.

So the more you could lay out in advance, what's your main hypothesis? when you're going to start analyzing? what's going to be your main, you know, analysis? what kind of -- you know, you going to trust SAR as our main driver, main -- mostly are interested in brain cancer and secondary and sub-type of a brain cancer and only thirdly just a screening tool for other cancers that's hypothesis generated, et cetera, et cetera.

I mean, I think all of those things would

be extremely useful. And you need, maybe ten years of follow-up, let's say, only then you will, you know, really

-- so when you -- I think it's useful to kind of try to lay all of this way in advance rather than asking people to struggle with it later.

It's -- it adds to scientific credibility and quality of the study all around, I think.

DR. LOTZ: Yeah.

DR. BOWMAN: But that's clearly going to take time to put the package together and to get the

funding, cause the cohort approach, a large part of the investment is up front in recruiting the cohort and getting in place what you need to follow it up.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: And even though some of the exposure assessment could be deferred to some degree, still you're going to need, you know, like you say --

DR. KHEIFETS: How to do it on the --

DR. BOWMAN: -- a road map as to where you go before you can get started with that part.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: So it's -- if you're going to do -- you know, if the cohort study is judged to be a priority, you really have to, you know, get people started looking, you know, developing the entire proposal and evaluating that and going, you know, the whole nine yards, as well as having the funding to --

DR. KHEIFETS: Right.

DR. BOWMAN: -- carry it off.

DR. KACZMAREK: There's a real case to be made that for a subset of the cohort, you really want to do a more extensive investigation than their exposure has been alluded to. You don't want to depend solely on billing records. You're going to have substantial non-

exposure mis-classification, or at least there's a

potential for that to occur.

DR. KHEIFETS: Oh, for sure. I would say that billing record study would be of no interest, in my opinion. To do another billing record study seems clear that is unuseful. We have them. They're available in a couple of places, so I would say that that would not be something -- I mean, as a cohort enumeration, it's fine. But not as an exposure assessment tool.

DR. OWEN: I'm sorry? As a what?

DR. KHEIFETS: As a cohort enumeration.

DR. OWEN: Enumeration.

DR. KHEIFETS: To define -- to define a cohort, you know, you could use billing records or whatever. But you have to do methodological work to make sure that -- who you missed, who you included, you know, is there over-representation; for some reason people have ten phones. Do people have more than one cellular phone?

DR. OWEN: Sure.

DR. KHEIFETS: Are there?

DR. OWEN: Are there?

DR. KHEIFETS: Are there people --

DR. OWEN: Oh, yeah.

DR. KHEIFETS: -- that have more than one cellular phone?

DR. OWEN: Oh, are you kidding?

MR. DESTA: You can have more than one number on a single cell phone.

DR. KHEIFETS: So you need to link those into one person, kind of?

DR. OWEN: I know, personally, know of several people that have --

DR. KHEIFETS: So they carry more than one phone?

DR. OWEN: I know of several people who carry two or three.

DR. KHEIFETS: And why? What's the reason?

DR. OWEN: Well, there's a lot of different reasons. Some are for different purposes. Some are for, the more obvious one, of travel and coverage in different areas, where different technologies are used. Some I don't know why. That's probably the biggest group.

DR. KHEIFETS: So you need to clean all of

those things up, you know. So it won't matter in most cases, but --

DR. BOWMAN: Right.

DR. KHEIFETS: -- you'll have few.

DR. BOWMAN: And it would seem to me, the real power of the prospective study would be that you can get the dosimeter phones in the hands of as many of the

cohort as possible, at least, or part of the year, a month or so out of each year. And that, in getting that kind of data together, would clearly provide you with a heck of a lot better exposure assessment than what the Interphone Study is even doing.

And then again, of course, would be a big investment, both in the phones, as well as in the personnel to get it into the hands of the subjects.

DR. KHEIFETS: You could -- you could have them have a free month's of service three months after they return the phone, or something like that. They have to give the phone back, and then three months after, a thousand --

DR. BOWMAN: And that affects their exposure.

DR. OWEN: Right.

DR. KHEIFETS: But, no -- oh, yeah. Well, it would afterwards.

DR. LOTZ: Exposure goes way up.

DR. KHEIFETS: That's true. Not a good idea. Not a good idea.

DR. BOWMAN: Your incentive can't have anything to do with phone use.

DR. OWEN: Yeah. I was wondering about that.

DR. KHEIFETS: Not a good idea. I was trying to make it so that it's not during that particular month we were going to use the data, but --

DR. LOTZ: What I was even thinking is --

DR. OWEN: So what do you do, is ensure that it didn't skew the data you collected. But still increases people's exposure.

DR. KHEIFETS: Right. Right.

DR. LOTZ: I was even thinking, well, you could offer them just the average number of minutes they normally use. But if they were looking at their cost, then they'd be able to add more minutes.

DR. KHEIFETS: No, no.

DR. LOTZ: Still, that wouldn't work.

DR. KHEIFETS: Okay. I guess the incentive is, you're going to take their phone away for a month.

DR. BOWMAN: That still isn't going to guarantee you're going to get the dosimeter phone back.

DR. KHEIFETS: that's true.

DR. LOTZ: Joe, I -- it was my impression that in the IARC Study, there -- while they have a relatively small number of the dosimeter phones, they're going to move them around to different subjects so that

they get more assessment than just --

DR. BOWMAN: Yeah.

DR. LOTZ: -- that one group?

DR. BOWMAN: Right.

DR. KHEIFETS: Do they give any incentive, or not?

DR. BOWMAN: Well, one of the things I should have read more carefully, but haven't.

DR. KHEIFETS: You know, participation is becoming the huge problem, in general, all over the world.

DR. LOTZ: You mean --

DR. OWEN: Yeah, in the studies in general, yeah.

DR. KHEIFETS: In the studies, yeah. So, and with the people who have phones would tend to be really busy people, I would guess. Or at least they perceive themselves as very busy, so they need a phone while they're driving.

So, you know, I think that among them, participation might even be worse than among other people. So it's just -- I mean, it's better in the U.S., but it's also getting worse in other places too.

DR. BOWMAN: Would you want me to read the study population recruitment?

DR. KHEIFETS: Um-hmm.

25 DR. BOWMAN: It is proposed that a

specially constituted cohort of individuals who are mobile phone users be asked to participate in the validation study by, one, authorizing the network providers to prospectively record and release information of actual phone use patterns, and, two, agree to be interviewed at some point following the end of the monitoring period by a network -- by the network operators.

If possible, a sample of the cohort should also be willing to use a software-modified phone for a period of one month.

The participants in the validation study will generally be distinct from those taking part in the Interphone case control study. The objective is to recruit at least 100 to 150 persons in each study center; and 50 of them would use the software modified phones. Ideally, this would be a random sample of cell phone users.

If this is not possible, then attempts should be made to gather a convenient sample that is relatively representative of the Interphone Study population with regard to gender, urban and suburban, rural residents, SES.

Subjects for the validation study should be between ages 30 and 60; possess sufficient language

abilities to consent to participate in the study and to

complete the questionnaires; be a resident in the study locality and to the end of the validation study; be likely to use a mobile phone at least once a week; be the main user of the nominated phone; use only the nominated phone for the majority of his or her calls; and consent in writing.

Further, volunteers who agree to use the software-modified phones should have mobile phone provided through pre-payment or contract arrangements and be able to transfer their usual SIM cards to an SMP.

DR. OWEN: Software-modified phone.

DR. BOWMAN: Yeah, to a software -- so I don't know what an SIM card is. I guess --

MR. DESTA: SIM cards --

DR. OWEN: Yeah, it's a SIM card. It's the more usual -- it's not a kind of the technology here. It's the smart card thing, that you --

DR. BOWMAN: Oh, it's a programmable --

DR. OWEN: -- so that you can use -- you know, you can pick up any phone, you put your personal --

DR. BOWMAN: Okay.

DR. OWEN: -- card in there and --

DR. BOWMAN: Okay.

DR. OWEN: -- you're billed.

DR. BOWMAN: Within each country, the

group of 50 users should be chosen to include people involved in a variety of different work and user activities, blah, blah, blah.

Usage while in motion, either in a train or car, should be covered, as well as stationary usage in office or home. So that's subject selection.

DR. OWEN: I was wondering, if you were -- say you were trying to get, again, a comprehensive look at the needs for exposure assessment, is there any danger that if one were designing exposure assessment for use in the cohort studies, that you would altogether miss the kind of information that you need if you were doing case control studies?

Not that I think there is; but it's a question that needs to be answered.

Another way to state it is, if you were designing free-standing exposure assessment studies, are there different things you would ask, depending on whether you were going to use that information for case control or cohort? Or is it reasonable to expect that anybody that came up with a comprehensive exposure assessment study would be collecting all the data likely to be useful in subsequent studies, either case control or cohort?

DR. KHEIFETS: No, I -- well, I mean,

there are differences, as we've discussed before. And

you're going to have brain cancer cases, that's, you know, especially for the rapidly fatal brain cancers, you're not going to have cases, you're going to have proxies.

So the kind of information you could ask of proxies might be very different. If you have cases that mentally are not, you know, their disease has lent to change in their mental ability to recall or answer questions or whatever, that would be an issue too.

If you're doing the case control studies, I would -- and recall bias is a huge issue, I would throw in some questions that, I don't know, about walkee-talkees, or -- I've already said -- I don't know. -- head phones. I don't know. Something about walkee-talkees, perhaps.

Some sort of things that the layman might tend to associate with potential problem, both where you know that there is not going to be substantial RF exposure from that, just to get a gauge of how much of your -- if nothing else, you could adjust for that in some of the analysis, if you do find a strong recall difference. Which most of the time people actually don't find a lot of recall difference. But it's a huge fear, because it's so possible. And even a little bit of recall bias could really, you know, screw up -- I mean, bias is really bad.

It's worse than random errors essentially.

But, you know, so, you know, you throw in something like that. And in the big study, you know, the kind of questions and -- you know, you can't do a one hour computerized questionnaire for 200,000 people, most likely.

DR. BOWMAN: Right.

DR. KHEIFETS: So you wouldn't be able to do that. You would do it only in a case control study.

So you'd have to --

DR. BOWMAN: So a lot of -- I mean, the more detailed exposure assessment, the questionnaire part, almost by necessity, would have to be a nested case control study.

DR. KHEIFETS: Or use some sub-sample. You know, I mean, I don't know. You could -- it doesn't have --

DR. BOWMAN: Or you --

DR. KHEIFETS: -- to be nested case control. I mean, if you enumerate cohort based on some characteristic, you could, in principle, then stratify by those reported characteristics and sample randomly from that population to do a much more detailed assessment. You know, so it's an ongoing basis.

You could sample, you know, half a

percent

or whatever number of that big cohort, you know, and then

just do -- but so I want the heavy phone users and I have -- want the lowest. And I want whatever you think are going to be important things. And you just stratify on that and do a weighted sample or non-weighted sample and --

DR. BOWMAN: And what do you do with the people who do get cancer? Do you then do the retrospective questionnaire?

DR. KHEIFETS: Not as part of -- no -- well, then if you -- then you can go on. And that would be just for full cohort characterization. But you don't have -- I mean, you can't do different for the cases and controls.

DR. BOWMAN: Okay.

DR. KHEIFETS: So you just use that information to characterize everybody or cases and controls based on whatever information you have for the whole cohort or whatever sample you have. But you supplement it with your information and exposures.

So you say, if a person answered that he

used the phone for so long in 1980, I'm going to assign whatever exposure is. And you do the same thing for cases and controls.

And then if he used a phone for half an hour average in 1990s, you know, the technology changed,

number of base stations changed, and all this I've learned. So, therefore, I'm going to assign a different number now again to cases and controls. And I just do much better exposure assessment.

DR. BOWMAN: So the --

DR. KHEIFETS: For that.

DR. BOWMAN: Right.

DR. KHEIFETS: Alternatively, then you do a nested case control study, which you could still use that information gain. But you just have to -- you just can't use more information for cases and controls. I mean, you can't use any of the -- even if they happen to be part of your sample, you can't use that for that.

DR. BOWMAN: So a key question is, what information do you collect about all cohort members? That's --

DR. KHEIFETS: Well, it's whatever you define the cohort with. Yes, that's right. But, I mean, that's whatever, you know, we could handle. I mean, it has to be very, very -- I mean, ideally, it's based on some records. But alternatively, you have some sort of, I guess -- I mean, I don't know. I would have to think about it and pilot it. I -- I mean, you just --

DR. OWEN: You might not be able to

answer

that question without having piloted --

DR. KHEIFETS: Yeah.

DR. OWEN: -- you know, to do an exposure assessment, piloting --

DR. KHEIFETS: But whatever you thinks going to be --

DR. OWEN: -- validation.

DR. KHEIFETS: -- very predictive of your exposure. I mean, and there were -- you can get a good handle on, and you basically use that. So --

DR. BOWMAN: Well, certainly a very important question is, how much further can we go in just the billing records for the entire cohort?

DR. KHEIFETS: Yeah, probably not much further. But that -- that is a very important question. But it's -- I mean, those things have to be piloted, you know, in terms of people -- do people answer honestly certain questions. You know, would they -- what kind of response you going to have?

So it's -- is it more than -- I mean, we've all have calls, we have to take five minutes of your

time. And you go, not right now. I'm really not home. I really am not. I really did not answer the phone. So it's, you know, people just want to get off the phone. And I think that they will say whatever just to get off the phone.

It's hard. I mean, it's not going to be -- it's not easy.

DR. BOWMAN: And that kind of consideration raises, in my mind, why is the cohort study so much dramatically better than the uniform case control model? Certainly, it will give us population-based exposure data to a certain degree.

DR. KHEIFETS: Well, it's better, because you can address many outcomes.

DR. BOWMAN: Okay.

DR. KHEIFETS: And it's better because you don't have a potential of bias due to control selection.

DR. BOWMAN: Yeah, the discussion we had earlier. But the exposure assessment may not be, you know, dramatically better than --

DR. KHEIFETS: It would be worse.

DR. BOWMAN: Right.

DR. KHEIFETS: Yeah. But I don't know. I mean, it would be interesting to know, in this Interphone Study, I mean, what do they do for a lot of brain cancer

cases?

DR. BOWMAN: Good question.

DR. KHEIFETS: I mean, I hope they do -- I hope they do proxy interviews for controls if they are doing it for cases.

DR. OWEN: I know they have proxy interviews in the two recent case controls. But I don't remember what the frequency of that was within the --

DR. KHEIFETS: And they didn't really present any data. They say it really didn't make any difference. But I don't think they had information on proxies.

DR. BOWMAN: The impression that I've gotten is that they do the best interview of the cases.

DR. KHEIFETS: But Ron just said that three to four weeks fatality for some sub-types.

DR. BOWMAN: For sub-types, right.

DR. KHEIFETS: So they are not doing those, right?

DR. KACZMAREK: Not three or four weeks.

DR. KHEIFETS: Well, it would be impossible.

DR. KACZMAREK: Weeks as opposed to less than a year.

DR. KHEIFETS: Right.

DR. KACZMAREK: No. But it can certainly be a very rapid progressively downhill course for many gliomas --

DR. KHEIFETS: And you would not be able to --

DR. KACZMAREK: -- as opposed to --

DR. KHEIFETS: -- actually -- I mean, people would lose their --

DR. KACZMAREK: Right. Yes.

DR. KHEIFETS: -- faculties as well.

DR. KACZMAREK: Long before, unfortunately, the patient expires, you may be unable to communicate the information properly --

DR. KHEIFETS: That's right.

DR. KACZMAREK: -- from mere loss of mental faculties. But this varies by tumor type. I mean, things like meningiomas are slow growing.

DR. KHEIFETS: Right. Right.

DR. KACZMAREK: And they can be shelled out.

DR. KHEIFETS: Right.

DR. KACZMAREK: And acoustic neuromas are just benign overall.

DR. KHEIFETS: Right.

DR. KACZMAREK: But there are certainly sub-types of tumors where the course is very rapidly progressive. And there's a good chance you're not going to get information from the subject.

DR. KHEIFETS: Leonard lost ability to really communicate. I don't know how he would do with the

questionnaire. I mean, he couldn't find words way before he died. I mean, but he -- he couldn't find words. He knew them. And it was very frustrating. And he was -- just he couldn't. And then later, he lost a lot, a lot of -- I mean, it just --

DR. OWEN: So is it the case then that we have very little information on how much worse having a proxy answer the questionnaire is than -- or how much less valid maybe is a better -- you know, how much less --

DR. KHEIFETS: We know it --

DR. OWEN: -- valid it is as of --

DR. KHEIFETS: We know proxies are much worse.

DR. KACZMAREK: Right.

DR. OWEN: Yeah.

DR. KHEIFETS: The question is, are they --

DR. BOWMAN: Yeah, that's been studied.

DR. KHEIFETS: -- are they biased or not. And in the ELF area, we have one study by -- where there seem to be a total proxy effect, in my opinion, where, you know, if you look at the analysis, it was completely due to proxy response that was in effect at which --

DR. LOTZ: Which one was that?

25 DR. OWEN: Parental --

DR. KHEIFETS: The appliance use that was. But this is similar. This is also use of -- somebody else using --

DR. LOTZ: It's an appliance.

DR. OWEN: Yeah.

DR. KHEIFETS: It's an -- yeah. I'm just saying that it was totally, you know, it's a question about shavers, electric shavers, or -- and other appliances, which was totally based on proxies, proxy response. If you took that away, there was hardly no -- but that's just a dramatic example.

People always worry about recall bias and the proxy response. They, you know, don't -- can't always show that whether it's present or to what extent it's present, so -- but especially for brain cancer, I think it's worse than for other diseases. You know, if you had leukemia let's say, or something like that, that could be better for two reasons. I mean, the patient survives longer and he is not -- his brain is not affected. So he's able to respond longer too. So just I think is a bigger problem here potentially.

DR. OWEN: So I'm trying -- it may just be maybe I'm caught in the semantic pitfall or something. I understand it's a big problem. I'm trying to rephrase

25 that in terms of, you know, can that problem be quantified

or what data could be collected to address that problem. Or is it, you know, we just don't know?

DR. KHEIFETS: No, no, no. Like, for example, what I said is that you need to collect information, proxy response, from controls too. You're going to use proxy for cases, and that's very rarely done. But you should do -- you should collect -- because people always think better, you know, if I can ask a person, why should I be asking --

DR. OWEN: Okay. Got it.

DR. KHEIFETS: -- a proxy. But the point is, you want -- it's more important to have --

DR. OWEN: -- the same kind of data --

DR. KHEIFETS: -- less biased information than the more precise information.

I mean, in epidemiology, whatever you do is always trade off between bias and precision, basically. I mean, you just go, do I want bias or do I want precision, you know.

DR. OWEN: Um-hmm.

DR. KHEIFETS: And so --

DR. KACZMAREK: It's just much less of a problem for a cohort study, because you're enrolling the subject in the study when he's still healthy.

DR. OWEN: Right.

DR. KACZMAREK: In a case control study, your cases are being enrolled after they've been diagnosed.

DR. OWEN: Right.

DR. KACZMAREK: So that's why there's an advantage to using both approaches.

DR. BOWMAN: It seems to me that to the extent that you could gather more data than you're going to get from records from the cohort, if from no other basis than a sample every year, and this would include both giving them software-modified phones and asking them a questionnaire, you know, administrative questionnaires on the order of the Interphone questionnaire.

To the extent that you could do that across the cohort, you'd improve your --

DR. KHEIFETS: Sure.

DR. BOWMAN: -- information a lot. Now, to what degree that could be extrapolated to the actual cases on the bases of, you know, the records that you have for everybody, that I'm not quite so sure about. I really haven't thought that through.

DR. KHEIFETS: Well, I think you have to model it. You know, I mean, you have to have some common, you know, common things on everybody in the cohort that

you can use to --

DR. BOWMAN: Right. Yeah.

DR. KHEIFETS: -- supplement --

DR. BOWMAN: Right.

DR. KHEIFETS: -- you know, for the information, you know, according to how it best fits your drivers.

DR. BOWMAN: Right.

DR. KHEIFETS: Like, you know, for SES or whatever you can, you know, have. Whatever you can have inexpensively on individual basis, you get it.

DR. BOWMAN: Right.

DR. KHEIFETS: And then the rest you have to supplement.

DR. BOWMAN: And again, the tradeoff between precision and bias, you could also do a sub-analysis just using cases who have the more detailed exposure assessment. Now, how much of that you'd have to do in order to get a useful result is another question.

DR. KHEIFETS: And controls.

DR. BOWMAN: Well, I mean, your -- what I'm envisioning is that you would sample, like you said, maybe half percent --

DR. KHEIFETS: Right. Right.

DR. BOWMAN: -- of the cohort. So you --

DR. KHEIFETS: Right. Right. But you

then compare not to the whole cohort.

DR. BOWMAN: And then you'd follow it up for --

DR. KHEIFETS: Right.

DR. BOWMAN: -- ten years. At the end of the ten years, you have so many cases of cancer --

DR. KHEIFETS: Right.

DR. BOWMAN: -- you can do the analysis both on the basis of records that you have for the entire cohort --

DR. KHEIFETS: Right.

DR. BOWMAN: -- and include all the cases. Or you can just limit yourself to the cases that have been --

DR. KHEIFETS: If you have enough.

DR. BOWMAN: -- sampled at some point.

DR. KHEIFETS: If you have enough cases.

DR. BOWMAN: Right.

DR. KHEIFETS: Yeah.

DR. OWEN: Would it be -- do you think it

would be feasible to try and focus on collecting information that really just sort of studied the proxy effect more? Or is that something specific for these type of exposures?

You know, if you were doing a sub-study or

whatever this -- you know, sub-cohort exposure assessment, do you think it would be really difficult or would it be feasible to collect, at the same time, you know, not only the primaries, but the proxies for questionnaire information?

DR. KHEIFETS: Well, if you do a cohort, that's not an issue. It's only in the case control studies --

DR. OWEN: Yeah --

DR. KHEIFETS: -- that the proxy issue is an issue.

DR. OWEN: But you want the information for -- I mean, what I'm saying is, you --

DR. KHEIFETS: You could do it in any -- it's just the methodologicals. You're proposing is just doing a methodological study. You could --

DR. OWEN: Or at least that's what I'm trying to isolate essentially.

DR. KHEIFETS: Which I think has nothing -- I mean, doesn't have to be linked to the cohort. It could be just a methodological study. You get hundred cell phone users or 200 or whatever, and have their proxies and see how well they respond to the same question.

DR. OWEN: Well, see but -- let me phrase

it a different way. Do you think that that type of methodological study would truly uncover most of the problems with proxy? Or are the -- you know, is it compounded --

DR. BOWMAN: Well, it's not -- we know --

DR. OWEN: -- by the fact that --

DR. BOWMAN: -- that there's problems.

DR. OWEN: Yeah.

DR. BOWMAN: What you would want would be data valid enough to make inferences as to the impact of the proxy bias on the outcome and inferences, you know, that at the end of the day when an IARC Study group or whatever sits down and looks at it, that they would base their numbers on that inference, as opposed to the straight up conventional analysis.

DR. KHEIFETS: Yeah. I mean, what -- I mean, maybe we -- maybe you want us to think -- I don't know about today, but maybe tomorrow. But, I mean, maybe you want us to think, in addition to what we've been thinking about, what would be kind of good informative hypothesis testing studies.

In addition to that, we could think about totally different issues. What kind of studies would be

good to try to address the limitations of existing studies? Could we do small, inexpensive methodological

studies that would be complementary or, you know, informative in terms of the existing studies that have been published?

And that would be a different question than designing sort of a de novo study, the best you can do at this point in the de novo study.

And I mean, there are issues like hospital controls that maybe we want to address for the existing -- the studies that are being published. Like, let's say with Muscat's Study. I mean, if that was the study that was of particular interest for whatever reason, then you know, we could give some thought, I think, to what kind of methodological work would be useful in addressing the weaknesses of that study. We should think --

DR. OWEN: I think that kind of thinking would be very useful.

DR. KHEIFETS: What are the main weaknesses in that study? We talked a lot about

exposure
19 assessment. Could things be done to supplement what is
20 there in terms of the exposure assessment. And it's
never
21 going to be perfect. Because whenever you go to a
22 different population, it will -- it could be
informative,
23 but it's not going to, you know, be definitive or answer
24 all the questions or anything like that. It's just it's
25 not within the realm.

But you certainly could do, you know, try to see -- we could think, can we address -- can we address an exposure assessment issue? Could we improve on -- you know, could we suggest anything? Is there a selection bias issue? Could we improve on that? Is there a better analysis? You know, could there be a better analysis done?

I mean, I don't -- there all those issues that we could specifically think would be -- having that particular paper would help, actually. Maybe we can get a copy of it for tomorrow or something.

DR. OWEN: Somehow we can, yeah.

DR. BOWMAN: Which one?

DR. OWEN: Muscat.

DR. KHEIFETS: I mean, for a dollar a page, I can have somebody fax it to me right now.

DR. BEARD: They charge us to get a fax.

MR. DESTA: I'll call the office and

try
to get someone to fax it.
DR. LOTZ: I'm trying to think whether I've got it handy.
DR. KHEIFETS: If you can't, I will --
DR. BOWMAN: Um-hmm?
DR. LOTZ: I'm trying to think whether I have it handy.

DR. OWEN: Would Barb have it handy?

DR. LOTZ: Yeah.

DR. OWEN: Could you get her to --

(UNKNOWN SPEAKER): I've got a -- I'll make a copy of it for you.

DR. KHEIFETS: Oh, great. All right.

DR. OWEN: Thanks.

DR. KHEIFETS: It's a dollar a page.

DR. LOTZ: Yeah, she might.

DR. OWEN: Yeah. Well, I guess we don't have to worry about it now.

DR. LOTZ: Yeah. Right.

DR. KACZMAREK: But there is an issue beyond all the points that you raised, which I agree with. And that is, there is a need for the study participants simple to have a longer mean duration of use. I mean, we could do all those things with the existing data set, and you still --

DR. KHEIFETS: Sure.

DR. KACZMAREK: -- have that limitation --

DR. KHEIFETS: That is true.

DR. KACZMAREK: -- that duration of use is so limited.

DR. KHEIFETS: I totally agree.

DR. KACZMAREK: I mean, generally less

than three years.

DR. KHEIFETS: I totally agree.

DR. KACZMAREK: There's a real need to conduct studies where the mean duration of use is closer to, say ten years.

DR. KHEIFETS: Um-hmm, I totally agree. That's --

DR. OWEN: I guess part -- one of the reasons that the train of thought you were just on was so appealing to me is that it's nice to have things modularized to the extent that it can be, because it's -- you could set off to try and design the perfect study. But if you can't actually follow through and conduct a perfect study, then where have you gotten to?

Whereas, if you could break it up into chunks into useful pieces, then you can -- you can use as many or as few of those as you're able to use. Nobody knows what the future holds. And so --

DR. KHEIFETS: Well, and I think, in that respect, again, this is going to be very much dependent on us believing in SAR or whatever, which always could come back to haunt us.

But in principle, I mean just getting the kind of information that says that only exposure to the

brain is, you know, of interest, you know, I mean, there

is ten order -- some number of orders of magnitude higher than exposure to anywhere else.

DR. BOWMAN: I don't think we're totally locked in to SAR in the -- like in the Interphone. What -- the three pieces that I'm -- that we're stringing together is the frequency of use and the model of phone used, from the questionnaire, the distribution of power from the software-modified phone study, and, lastly, the dosimetry.

Only that last part is totally linked to SAR.

DR. KHEIFETS: No. The frequency of use we just talked about, right? I mean, the frequency of use assumes that what you get during the use is a lot more than what you get during a long time beeping that you're getting just, you know, from sitting in your pocket, for example.

DR. BOWMAN: Well, that's true whatever EMF exposure metric you work with; whether it's SAR or, you know, like exposure to a modulated frequency. Any

other kind of physical exposure metric, I could imagine, you can still get from, you know, you know the model of the phone. You are making assumptions as to what the orientation of the phone is relative to the rest of the body. And, you know, it's straight forward enough to go

measure the fields and do any other kind of modeling, other than SAR. Now --

DR. KHEIFETS: Are you collecting information on how much the phone is on, without its being --

DR. BOWMAN: Well, that's, you know, again, to fully address that, you would have to be doing something like the prospective study, where you were handing out the software-modified phones to a sample of the cohort, to fully address that.

DR. KHEIFETS: Yeah, but I mean, you could -- we could certainly -- it seems to me, maybe somebody knows that -- those answers, but we certainly don't. I mean, with small exposure assessment studies, you could answer a lot of those questions.

DR. BOWMAN: Oh, right. So I --

DR. KHEIFETS: You know, modular --

DR. LOTZ: Right.

DR. KHEIFETS: I'm just saying that in the modular -- he was asking for small steps. I'm trying to kind of --

DR. LOTZ: Right.

DR. KHEIFETS: -- talk about small steps that would certainly be very useful, but provide good information and would help in deciding --

DR. BOWMAN: And there I'm totally in agreement with you.

DR. KHEIFETS: Yeah.

DR. BOWMAN: I think that all this morning, we were sort of, as we were walking along, it sort of popped out at various points, that exposure assessment data collection would be very important. And what you also brought up here is methodologic studies as to ways of addressing the various sources of bias and sampling that's going on.

One thought that I had is that basic inference is being used to a certain degree to modify your risk estimates on the basis of sample data about the various sources of bias. And that would be another methodologic, you know, area that could be investigated. And that could all go on while the cohort is established and regular sampling is happening.

The only thing that sort of worries me is that you still have the big up front expense of enumerating the cohort and starting to collect data on a regular basis. And that's going to be a big ticket item. And, certainly, you can enhance the outcome as you go along by doing sub-studies and methodologic studies, so that when the time comes to actually analyze it, you've

25 got a much better package than you would have had at the

beginning.

But you still have to make a pretty big long-term big ticket commitment to establishing the cohort and following it up.

DR. KHEIFETS: But I think that the -- I mean, I think that the major -- I mean, I might -- let me just propose this to the group for some discussion.

I mean, from what I've heard, it seems to me that we all feel that there should be things that are -- that -- I mean, there should be studies that should be undertaken, sort of one -- you know, I don't know. If somebody does -- disagrees, then let's discuss that.

But from what I have heard, you know, that's kind of the consensus.

Now, then the big decision is, do you go with the cohort-type approach or you go with a case control approach. And that's a real kind of differentiation. And there are certainly, you know, a lot of methodological small things that I think we could all easily agree that would be useful to do.

But then there is a big money, you know, issue and complexity. And there are advantages to each approach. You know, one is not clearly preferable to the other. But at the end of the day, what I think should decide -- it's really is not so much of a scientific

issue, it's more of a sort of policy perspective issue.

Do you want to have -- whoever pays for it, do they want to have a better information on one outcome, you know, very expensively, or do they want to have a more accrued information with a broader stroke?

And, you know, we could certainly outline all the issues involved in kind of a tradeoff in making those decisions. But I don't think it's really so much a scientific decision.

I mean, do you want to -- you know, do you want to be pro-active and try to look at all potential possible outcomes? If that's the case, you don't have a choice, you have to do a cohort study.

DR. OWEN: Yeah --

DR. KHEIFETS: Or do you want to be limiting and kind of trying to understand the best you can, you know, the one thing that has been brought up most often, which is the brain cancer?

DR. OWEN: Yeah. The purpose of this meeting is not to try and choose a path or decide upon a path. And it's much more useful to come up with specific -- to discuss the elements that could address specific problems, in recognition that there are these two different paths that could be taken --

DR. KHEIFETS: Make our job easy.

DR. OWEN: Yeah.

DR. KHEIFETS: Then, I mean, that's, you know, certainly there --

DR. OWEN: I mean, there's -- I'll just back up one step. There's a much larger context. It's, you know, one has not only to decide case control versus cohort. You know, then one has to decide, you know, laboratory --

DR. KHEIFETS: Whether it's epidemiology --

DR. OWEN: -- versus epidemiology.

DR. KACZMAREK: Right.

DR. OWEN: And so there's --

DR. KHEIFETS: There's no question.

DR. OWEN: But this meeting is only to discuss --

DR. KHEIFETS: There is no question about it.

DR. OWEN: This meeting is only to discuss the epidemiology. And so there's no need to talk about --

DR. LOTZ: You like those lab studies.

DR. KHEIFETS: I love them -- I mean, again, they are only informative in the supplementary fashion. I mean, people have to recognize which, you

know, that the laboratory studies will be informative only

if they are positive. We hate to hear that, but that's the case.

DR. OWEN: Contrary to United States regulatory usage.

DR. LOTZ: Yeah.

DR. KHEIFETS: And they could be fantastically useful if they are positive.

DR. OWEN: Um-hmm.

DR. KHEIFETS: There is no question, then you could try to -- only if they are reproducibly positive. Not -- not like you see -- you don't see it or something. If they are negative, they're not going to be driving it in any kind of way. So --

DR. OWEN: Of course there's a large precedent in regulatory use for relying on negative laboratory data too, for decision making. And so while you may be correct in the absolute sense, in --

DR. KHEIFETS: Only in the --

DR. OWEN: -- practice it is used quite a bit.

DR. KHEIFETS: Well, only because there's an absence of epi data --

DR. OWEN: Um-hmm.

DR. KHEIFETS: -- in those cases.

DR. OWEN: Yeah.

DR. KHEIFETS: And there's not going to be an absence of epi data in this situation. There are going to be poor epi data anyways, so --

DR. OWEN: Poor epi data, is --

DR. KHEIFETS: Poor, yeah. So it's not a question, I think, of having epidemiologic data or not having epidemiologic data; it's a question of having the best epidemiologic data you can, which is still going to be very problematic.

But I don't think you can, you know, put out the technology and not have the data on -- I mean, the kind of widespread use. I mean, what you're talking about is probably kind of chemicals that are not that broadly used, that once you have something that --

DR. OWEN: Dioxin.

DR. KHEIFETS: There is epi data on that.

DR. OWEN: Yeah.

DR. KHEIFETS: So, anyway, that's my opinion.

DR. OWEN: The last meeting we had a

couple weeks ago, while we didn't have anybody register up front to make public comments, we did have somebody show up and want to talk. And we were able to work that in. And this is kind of the standard time slot where that kind of thing happens, is the last half an hour of the first

day, or something like that.

And so I just kind of want to note that I haven't -- nobody has asked me for time to -- you know, people outside the table, nobody has asked for time. But, you know, you're allowed to say something. It is a public meeting, you know. As long as you're not disruptive.

And, in fact, I hope that, in some cases, where we have sort have asked around the table and everybody said, well, we don't know, I hope if you do know the answers to the questions like that, that you'd volunteer them. It would be helpful. But, obviously, those are going to be the kind of things that I key on in my notes for follow-up, you know, directed follow-up to people by correspondence to pick up those pieces of information.

DR. KHEIFETS: In fact, I don't know -- I would be very interested in any perspectives that are

there.

DR. OWEN: Although I realize that people are frequently reticent to make a comment, depending on, you know, why you're here and whatnot. Thanks. I appreciate it.

DR. KHEIFETS: You have to make the offer again.

DR. OWEN: Maybe Abiy, you'll be able to

get them to run off a bunch of them, at least so that people will have them when we start in the morning. You know, I don't think, you know, given the time of day it is, that we're going to be able to --

DR. KHEIFETS: No, no. Yeah.

DR. OWEN: -- do anything with it at this point.

DR. KHEIFETS: Right.

DR. OWEN: But if we have it --

DR. KHEIFETS: Yeah.

DR. OWEN: -- before the start of the morning --

DR. KHEIFETS: Do you want to extend your offer to --

DR. LOTZ: Yeah, after you sent him out of the room.

DR. OWEN: Oh, sorry. I just -- what I just said was that nobody has come to me and asked me, you know, that they wanted time to say anything. And I was basically making sure that nobody was, you know, feeling like they were missing out on an opportunity.

I wasn't totally ignoring him, cause he was here for the meeting two weeks ago. So I figured if he really wanted to talk, he would have. We appreciate

the help, though.

What I -- I really appreciate, though, what you suggested a few minutes ago in terms of something to attack tomorrow in terms of generating a lot more input.

Depending on how long we can go with that kind of discussion in the morning, in terms of these more specific ideas of things that can be done, I would then try and briefly re-visit some of what we hit today in terms of trying to sort of provoke, after a night's rest, additional thoughts on areas that we've already touched upon, just to try and make sure we have some sense of completeness to the discussions.

But there's not -- we're not under a time constraint, in terms of, you know, coming up -- you know, writing a summary document and coming up with any kind of recommendation or anything else like that. So I think in the half day that we have planned for tomorrow, we've got plenty of time to finish our discussions.

Even though I think the F-R notice calls for a whole day tomorrow, we've got travel plans that basically call for a half-day meeting tomorrow. Most people, I think, are traveling out tomorrow. I guess you're not because you're going to be here for subsequent stuff.

DR. LOTZ: I have just one question with

respect to after the meeting. Do you anticipate sending the transcript and asking for comments on it at some point? Or how do you -- do you anticipate any follow-up from us to a written record of the meeting?

DR. OWEN: We will be getting the transcript files from this meeting, as well as the other one. And since it will be in an electronic format, we'll be able to email that out to everybody and ask for comments on it.

That doesn't necessarily mean that I expect everyone to -- you know, people may or may not want to read through transcripts. They're going to be lengthy documents. So it will be at your option. And there won't be any kind of implication that anybody here is responsible for their completeness or correctness.

And, in fact, for the meeting that we had in August, we basically provided the file to anybody who asked for it, leaving on it the label from the transcript company that said, these are, unedited, unreviewed. And so that's, you know, probably the pattern we'll take.

Because, you know, it's not our intent here to establish some kind of a, you know, a docket or, you know, anything like that. So, you know, we'll capture what we can capture with it. The main purpose of taking the transcript is actually because it's a public meeting,

for the interested public who's not able to attend, to be able to see the transcript.

Of course, we will be able to use it for checking back on the discussions. But --

DR. BOWMAN: If the -- as I understand it, the point of the meeting is to make recommendations --

DR. OWEN: No.

DR. BOWMAN: -- for the --

DR. OWEN: I was trying to make that clear. The point of the meeting is to collect scientific and technical input.

DR. BOWMAN: Right.

DR. OWEN: FDA has to make recommendations.

DR. BOWMAN: Right. Well, what I was thinking of, not that I'm -- you know, I'm not saying that we have any say over what FDA recommends.

But what I was thinking of is that in the course of the meeting, we've thrown out numerous proposals for studies, big, small, and in between. And what I'd just be interested in would be a list of, you know, the suggestions for research that we generated. And that would be an area where I'd be interested in maybe, you know, modifying or amplifying or correcting --

DR. OWEN: I think that would be --

DR. BOWMAN: -- what came out of the transcript.

DR. OWEN: I think that would be very useful.

DR. LOTZ: That would -- Russ, that would also be consistent with what you did last October, wouldn't it? That two of the discussion members themselves --

DR. OWEN: Yes.

DR. LOTZ: -- you sent a distillation --

DR. OWEN: Yes.

DR. LOTZ: -- of your --

DR. OWEN: With the --

DR. LOTZ: -- ideas, almost.

DR. OWEN: Right. And what -- with the sort of caveat, whether clearly stated or only implied, was that I was mainly looking for people to point out where it was wrong. By virtue of the fact that it was a distillation, obviously, there was no desire to try and re-expand it out to be completely comprehensive.

DR. BOWMAN: Right.

DR. OWEN: But, you know, I'm willing to take whatever input I can get. And so, you know, if people want to -- if I send this out -- send something out

and people come back with me, well, you forgot to note

that I said this and I said that, then I'm perfectly happy to -- that's useful input, to --

DR. BOWMAN: Well, I'm not so much interested in, you know, the completeness of the record. I'm more interested in, in the distillation that -- particularly in the distillation of research recommendations or, you know, critique of things like the cohort study idea, that there may well be things that I didn't, you know, say exactly right or you didn't distill it the way I would distill it. That's the kind of thing I'm --

DR. OWEN: No, that would be -- that would be useful. And that would be the kind of thing that I'd like to get in follow-up. But we don't' have an established timetable for this follow-up.

In the work that we did -- started in August, it was a much clearer picture before we even started the meeting, of what kind of things really needed to be done as direct follow-up to a particular study. There's a less clear defining line in this situation. So there's -- it's a more difficult task.

But there's a -- either way we still want to get as much -- as comprehensive an input one way or another as possible. How that is reflected in the

recommendations to CTIA for action at, you know, X point

in time is kind of a separate step.

DR. BOWMAN: Oh, yeah.

DR. OWEN: Separate and additional difficulty --

DR. BOWMAN: Right. And I have no desire to, or let alone claim any power over --

DR. OWEN: I was going to say, you know, we could easily ascribe blame, if you want to be more intimately involved in this.

DR. BOWMAN: No.

DR. OWEN: But, in fact, the other thing I wanted to point out now, especially in case I forget to mention it tomorrow, is that I invite, expect and desire additional input by correspondence that either occurs to you because it didn't occur to you here and it pops into your head later, send an email. Or, you know, maybe it's something that you didn't feel like you could discuss as full as you'd like to in an open public meeting. But that doesn't mean that you can't, you know, tell me in

correspondence what your thoughts are in more detail. And so I just want to invite that initial input, if you have it to offer.

DR. KHEIFETS: I think that it will be good to have that list kind of combined from the two meetings. You know, I'm sure things are quite repetitive

as well. So I'm just trying to just have one list to --

DR. OWEN: Yeah, and --

DR. KHEIFETS: -- you know, actually, if you wanted to, you could even solicit further input on the list in terms of the priority. Once people from both groups see the complete list organized in some fashion, they might be able to give you some way their sense of priority. And then you could exert complete control by the way you weight those.

DR. OWEN: Well, actually, I would be going -- I intend to go one step further than that, because these two meetings are one avenue of input. And I may have mentioned, you know, correspondence with people that aren't involved in either of these meetings is also something that we want to pursue in terms of getting input. But then going back out for sort of comment on what has come in --

DR. KHEIFETS: Yeah.

DR. OWEN: -- what has come in, is something that --

DR. KHEIFETS: Yeah, sure.

DR. OWEN: -- that I would -- that I

want

to do.

DR. KHEIFETS: The complete list, sure.

DR. OWEN: That it -- it does pose an

interesting situation. Because, as I mentioned earlier, the direction of the discussions at this meeting compared to the one two weeks ago has been surprisingly different to me. And so I think it will be of interest to both groups to see how things went in the two meetings and then to see any attempt at pulling everything together.

The prioritization input is something that I would like to see, mainly because if there turns out to be some line partway down through what FDA thinks ought to be done, you know, things above that line get done and things below that line don't get done, I want to make sure that the list is in the right order, you know, the best or most appropriate order.

DR. KHEIFETS: Um-hmm. Also, this just might be useful then for the future of activities of whoever wanted to pursue whatever they wanted to pursue from that list. Even though it's not going to get funded, it still might be -- just like we looked at the, you know, description of things from other groups. In terms of their research recommendations it might useful too.

DR. OWEN: Okay. A procedural question. What time should we try and start? Was it a strain for the people coming locally to get here for an 8:30 start, and would it be a strain to be here at 8:00 for a start?

DR. LOTZ: I'm pressed a little to be here

by 8, but 8:30's okay.

DR. BOWMAN: No problems with 8:30. I can get here a bit earlier.

DR. OWEN: Okay.

DR. BOWMAN: 8:15.

DR. OWEN: Yeah. Okay. Let's -- well, then let's strive for the compromise of 8:15. You know, I'll be in here at 8. We'll have additional copies.

Actually, that's an important thing. We'll have additional copies of the study for people to front-load with during the 8 to 8:15, or whatever. And then we can get off, and hopefully be finished -- if we finish by noon, will we be able to make the flights we're currently scheduled for?

MR. DESTA: By noon we'll make those flights, yes.

DR. OWEN: By noon. Okay. So we'll say we've got to be finished by noon. If we finished earlier, that would be livable.

Anything else that people think we need to

take care of? We've still got 15 minutes, if we want it. I think we -- everybody's looking pretty tired at this point. So I'm not sure how far we can get into new discussions. But maybe at least from a logistical point of view, I think we got some of that done very usefully

just in the last few minutes in terms of what kind of follow-up activities we might be able to engage in. If none --

MR. DESTA: I'd just like to point out, we're going to be in room 111 tomorrow.

DR. OWEN: Oh, yeah.

DR. LOTZ: 111. Sounds like a completely -- what, down the other hall or --

MR. DESTA: Yes, down the other hall.

DR. OWEN: Opposite end. Well, presumably the same sign will be -- you know, it may be almost transparent to us. Come down the steps and look for the sign. If you don't remember which way you turned when you came today, then it won't matter.

Okay. Thanks for today, and I'll see you all in the morning.

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(WHEREUPON, THE MEETING WAS

CONCLUDED FOR

19 THIS DATE AT 4:46 P.M.)

20 * * * * * * * * * * *

CERTIFICATE

STATE OF OHIO)
)SS.
COUNTY OF HAMILTON)

I, Debra A. Sprague, a duly qualified and commissioned court reporter and notary public within and for the State of Ohio, do hereby certify that the preceding 300 pages constitute a true, accurate and complete transcription of the meeting held as part of the Cooperative Research and Development Agreement, on the 2nd day of May, 2001.

IN WITNESS WHEREOF, I hereunto set my hand and official seal of office, this 18th day of May, 2001.

_____

DEBRA A. SPRAGUE, CVR
My Commission Expires:
August 12, 2001